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REGULATORY REVIEW PERIOD ACTIVITIES

The table below summarizes representative formal submissions and contacts between the drug sponsor and FDA throughout the regulatory review period. The table is not comprehensive as to every event corresponding to a given type of submission, nor does it reflect regular email and telephone contacts throughout the regulatory review period to discuss upcoming submissions and provide preliminary information. Following the table below is a more comprehensive list of regulatory review activities.

2002-06-03	**Initial submission date of IND No. 64,915**
2002-06-04	**Receipt date of IND No. 64,915**
2002-06-28	Revised informed consent form
2002-07-17	Updated information for drug substance and drug product
2002-08-30	Clinical protocol amendment
2002-10-29	Response to request for information – CMC
2002-11-06	Information amendment: clinical
2002-12-09	Response to request for information: 26 wk. animal toxicity studies
2003-01-02	Rationale & study summary for additional long-term protocol
2003-01-13	Response to request for additional information regarding IND
2003-01-14	Response to request re safety monitoring plans for clinical trial
2003-02-07	Protocol amendment: new protocol
2003-03-05	IND 15-Day ADR Report
2003-03-11	Investigator notification of IND safety report for elevated liver function tests
2003-04-01	Duration of chronic toxicity study
2003-05-02	IND safety report: follow-up
2003-05-15	Type B meeting request
2003-05-15	Fax requesting End of Phase II meeting
2003-08-05	Information package for 27 August 2003 meeting
2003-08-27	End of Phase II meeting with FDA
2003-10-08	New Phase III protocols
2003-12-02	Change in clinical protocol
2003-12-18	Request for special protocol assessment 2-year mouse carcinogenicity protocol
2004-02-13	Information amendment
2004-03-17	Pharmacology-toxicology 2-Year rat and mouse final protocols

2004-03-25	Type C meeting request
2004-05-06	Protocol amendments
2004-05-27	Orphan drug application: amendment
2004-08-09	Type C meeting request to discuss proposed changes to the ambrisentan program
2004-08-27	Initial written report: 15-day safety alert report
2004-09-27	Type C meeting information package
2004-10-13	Meeting
2004-12-07	Information amendment: pharmacology/toxicology: 2-year rat and mouse carcinogenicity
2005-02-15	New protocol
2005-03-09	Information amendment: pharmacology/toxicology: 2-year rat and mouse carcinogenicity studies
2005-04-05	Response to request for information
2005-04-12	Protocol amendment
2005-05-24	Converting ARIES-2 study sites to ARIES-1
2005-08-04	Information amendment: Chemistry, Manufacturing and Controls
2005-08-22	Data analysis plan for FDA feedback
2005-08-22	Fax re 7 day safety report - initial manufacturer's report
2005-08-25	IND safety reports
2005-09-07	Request for FDA review of QT/QTc study proposal
2005-09-12	Type C meeting request: development plan for biopharmaceutics and clinical pharmacology
2005-10-04	Information amendment: Chemistry, Manufacturing, and Controls
2005-10-04	IND safety report: follow-up to a written report
2005-10-13	Meeting re PK and clinical pharmacology
2005-10-18	New protocol and new investigator
2005-10-19	Teleconference re data analysis plans
2005-11-04	New protocol and new investigator
2005-11-07	Response to FDA comments on QT/QTc study design
2005-11-11	Protocol amendment: change in protocol
2005-11-11	Information amendment: pharmacology/toxicology 2-year rat and mouse carcinogenicity studies
2005-11-29	Data analysis plans
2005-11-29	Information amendment: pharmacology/toxicology
2005-11-30	Data analysis plan for population pharmacokinetic modeling
2005-11-30	Protocol: new protocol and new investigator
2005-11-30	Data analysis plans

2005-12-15	Teleconference re PK/PD development plans
2005-12-19	IND safety report: initial written report
2005-12-19	Protocol amendment: new protocol and new investigators
2006-01-09	IND safety report: follow-up to a written report
2006-01-13	Protocol amendment: change in protocol
2006-01-16	IND safety report: follow-up to a written report
2006-01-23	Protocol amendment: change in protocol
2006-01-27	IND safety report: follow-up to a written report
2006-02-09	Request for fast track designation
2006-02-21	Response to IND correspondence
2006-03-02	IND safety report: follow-up to a written report
2006-03-08	Type B meeting request: Pre-NDA
2006-03-15	Requirements and format of NDA
2006-03-23	Information amendment: pharmacology/toxicology
2006-04-19	Information amendment: pharmacology/toxicology
2006-04-21	Pre-NDA briefing document
2006-04-27	IND safety report: initial written report
2006-05-04	Information amendment: pharmacology/toxicology
2006-05-08	Response to FDA comments
2006-05-17	Type B meeting request: pre-NDA CMC
2006-05-19	Pre-NDA meeting
2006-05-26	IND safety report: follow-up to a written report
2006-06-02	IND safety report: initial written report
2006-06-14	Request feedback on non-clinical NDA format and content
2006-06-15	Information amendment: clinical CSR's
2006-06-28	CMC pre-NDA information package
2006-07-06	IND safety report: initial and follow-up written safety report
2006-07-26	Pre-NDA CMC meeting
2006-10-06	CMC- proposed commercial dissolution method
2006-10-13	Proposal for 4-month safety update
2006-10-30	IND safety report: follow-up to a written report
2006-11-07	IND safety report: follow-up to a written report
2006-11-28	IND safety report: follow-up to a written report
2006-12-07	Transfer of sponsorship
2006-12-13	**Submission of NDA No. 22-081**
2006-12-18	**Receipt of NDA No. 22-081**
2007-01-09	Teleconference

2007-01-18	Response to letter re submission of complete CRF's and filing process
2007-01-19	Telephone call regarding inspections at clinical sites that conducted Phase 3 studies
2007-01-22	Email regarding revised protocol document-presence of sponsors
2007-02-09	Teleconference re protocols for capturing lab values
2007-02-13	Response to questions on the distribution of ambrisentan and RiskMAP
2007-02-15	IND safety report: follow-up to a written report
2007-03-03	Request for meeting to discuss status of review of NDA 22-081. Update on Amendments submitted to NDA
2007-03-07	Unformatted prescribing information; option to resolve formatting
2007-03-20	FDA site inspection
2007-03-20	Response regarding request for efficacy & safety datasets
2007-03-21	IND safety report: initial written report
2007-03-22	Protocol amendment: change to protocol
2007-03-29	90-day teleconference
2007-04-03	Request for Meeting to discuss dosing interval
2007-04-10	Protocol amendment: new protocol and new investigator
2007-04-16	Response to questions regarding dissolution profiles
2007-04-19	Population pharmacokinetic (PK) data analysis plan (DAP) amendment
2007-04-19	Response to questions regarding bioanalytical assay issues
2007-04-23	Response regarding randomization
2007-04-24	Protocol amendment: change to protocol
2007-04-30	IND safety report: follow up to a written safety report
2007-05-02	Protocol amendment. New protocol and new investigator
2007-05-04	DDMAC promotional materials. Request for perspective review and advisory comments for product launch materials
2007-05-08	Protocol amendment: change to protocol
2007-05-25	IND safety report: follow up to a written safety report
2007-05-25	Meeting
2007-05-31	Proposed pediatric study request
2007-05-31	IND safety report: follow-up to a written report
2007-06-07	Protocol amendment: new investigators
2007-06-07	IND safety report: follow-up to a written report
2007-06-15	**Marketing approval letter for NDA 22-081**

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Product	Department	Country	Document Date	Book Number	Document Type	Document Title	E-Copy	Keywords
1	Regulatory	US	**7/20/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-199**	**S-199**	64,915
1	Regulatory	US	**7/10/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-198**	**S-198**	64,915
1	Regulatory	US	**6/28/2007**	Temp 113	FDA Submission - IND	**Annual Report. S-197**	**S-197**	64,915
1	Regulatory	US	**6/22/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-196**	**S-196**	64,915
1	Regulatory	US	**6/18/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-195**	**S-195**	64,915
1	Regulatory	US	**6/18/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-194**	**S-194**	64,915
1	Regulatory	US	**6/7/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-193**	**S-193**	64,915
1	Regulatory	US	**6/7/2007**	Temp 110	FDA Submission - IND	**Protocol Amendment. New Investigators. S-192**	**S-192**	64,915
1	Regulatory	US	**5/31/2007**	Temp 110	FDA Submission - IND	**IND Safety Report . Follow-up to a Written Report. S-191**	**S-191**	64,915
1	Regulatory	US	**5/31/2007**	Temp 110	FDA Submission - IND	**Other. Proposed Pediatric Study Request. S-190**	**S-190**	64,915
1	Regulatory	US	**5/29/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-189**	**S-189**	64,915
1	Regulatory	US	**5/25/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-188**	**S-188**	64,915
1	Regulatory	US	**5/18/2007**	Temp 110	FDA Correspondence - Letter (Fax)	L.Tanner/N.Stockbridge - The 7 Day Safety Report	**2007-05-18_64915_CORR_LETTER_FAX_LTANNER_NSTOCKBRIDGE.pdf**	64,915
1	Regulatory	US	**5/18/2007**	Temp 110	FDA Correspondence - Email	L.Tanner/D.Brum - Email with the 7-day Safety Report Documents attachment.	**2007-05-18_64915_CORR_EMAIL_DBRUM_LTANNER.pdf**	64,915
1	Regulatory	US	**5/18/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-187**	**S-187**	64,915

1	Regulatory	US	**5/14/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-186**	**S-186**	64,915
1	Regulatory	US	**5/8/2007**	Temp 112	FDA Submission - IND	**Protocol Amendment. Change to Protocol: Addendum to Protocol(s) AMB-320/321-E, AMB-222 and AMB-220-E. S-185**	**S-185**	64,915
1	Regulatory	US	**5/2/2007**	Temp 110	FDA Submission - IND	**Protocol Amendment. New Protocol and New Investigator. S-184**	**S-184**	64,915
1	Regulatory	US	**4/30/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-183**	**S-183**	64,915
1	Regulatory	US	**4/27/2007**	Temp 110	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-182**	**S-182**	64,915
1	Regulatory	US	**4/26/2007**	Book 109	FDA Submission - IND	**Protocol Amendment. New Investigators. S-181**	**S-181**	64,915
1	Regulatory	US	**4/24/2007**	Book 109	FDA Submission - IND	**Protocol Amendment. Change to Protocol: Replacement of Amendment No. 1.0 to Protocol AMB-323. S-180**	**S-180**	64,915
1	Regulatory	US	**4/11/2007**	Book 109	FDA Submission - IND	**IND Safety Report – Initial Written Report. S-179**	**S-179**	64,915
1	Regulatory	US	**4/10/2007**	Book 109	FDA Submission - IND	**Protocol Amendment. New Protocol and New Investigator. S-178**	**S-178**	64,915
1	Regulatory	US	**4/4/2007**	Book 109	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-177**	**S-177**	64,915
1	Regulatory	US	**3/22/2007**	Temp 111	FDA Submission - IND	**Protocol Amendment. Change to Protocol: Amendment No. 1 to Protocol AMB-323. S-176**	**S-176**	64,915
1	Regulatory	US	**3/21/2007**	Book 109	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-175**	**S-175**	64,915
1	Regulatory	US	**2/23/2007**	Book 109	FDA Submission - IND	**Protocol Amendment. New Investigators. S-174**	**S-174**	64,915
1	Regulatory	US	**2/23/2007**	Book 109	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-173**	**S-173**	64,915
1	Regulatory	US	**2/23/2007**	Book 109	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-172**	**S-172**	64,915
1	Regulatory	US	**2/15/2007**	Book 109	FDA Submission - IND	**IND Safety Report. Follow-up to written Report. S-171**	**S-171**	64,915

1	Regulatory	US	**2/2/2007**	Book 109	FDA Correspondence - Email	E.Smith/L.Tanner - Following on Transfer of Sponsorship from Myogen to Gilead, Sciences	**2007-02-02_64915_CORR_EMAIL_ESMITH_LTANNER.pdf**	64,915
1	Regulatory	US	**1/30/2007**	Book 109	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-170**	**S-170**	64,915
1	Regulatory	US	**1/30/2007**	Book 109	FDA Submission - IND	**Protocol Amendment. New Investigators. S-169**	**S-169**	64,915
1	Regulatory	US	**1/25/2007**	Book 109	FDA Submission - IND	**Protocol Amendment. New Protocol and New Investigator. S-168**	**S-168**	64,915
1	Regulatory	US	**12/19/2006**	Book 83	FDA Submission - IND	**Protocol Amendment. New Investigators. S-167**	**S-167**	64,915
1	Regulatory	US	**12/15/2006**	Book 83	FDA Correspondence - Letter	E.Fromm/L.Tanner. FDA Letter - Acknowledgment of the sponsor change.	**2006-12-15_64915_CORR_LETTER_EFROMM_LTANNER.pdf**	64,915
1	Regulatory	US	**12/12/2006**	Book 83	FDA Correspondence - Phone	L.Tanner/M.Robb. FDA contact report (phone call) - Clarify process for liaison with the Division during the review of NDA 022-081 and for submitting responses to reviewer questions.	**2006-12-12_64915_CORR_PHONE_MROBB_LTANNER_.pdf**	64,915
1	Regulatory	US	**12/8/2006**	Book 83	FDA Correspondence - Letter	N.Stockbridge/L.Tanner. FDA Letter indicates that Division does not recommend use of proprietary name LETAIRIS.	**2006-12-08_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	**12/7/2006**	Book 83	FDA Correspondence - Letter	N.Stockbridge/L.Tanner. FDA Letter - Clarification to Requirements 120-day Safety Update	**2006-12-07_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	**12/7/2006**	Book 83	FDA Submission - IND	**Other. Transfer of Sponsorship. S-165**	**S-166**	64,915
1	Regulatory	US	**12/6/2006**	Book 83	FDA Correspondence - Phone	L.Tanner/M.Robb - Confirm status of submission of NDA and transfer of sponsorship from Myogen to Gilead Sciences, Inc.	**2006-12-06_64915_CORR_PHONE_MROBB_LTANNER_.pdf**	64,915
1	Regulatory	US	**11/28/2006**	Book 83	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Safety Report. S-165**	**S-165**	64,915
1	Regulatory	US	**11/20/2006**	Book 83	FDA Submission - IND	**Protocol Amendment. New Investigators. S-164**	**S-164**	64,915
1	Regulatory	US	**11/20/2006**	Book 83	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Safety Report. S-163**	**S-163**	64,915

1	Regulatory	US	**11/7/2006**	Book 83	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Safety Report. S-162**	**S-162**	64,915
1	Regulatory	US	**10/30/2006**	Book 83	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Safety Report. S-161**	**S-161**	64,915
1	Regulatory	US	**10/24/2006**	Book 83	FDA Correspondence - Phone	L.Tanner/M.Robb - Confirm how RiskMAP materials are regulated and obtain status of review of trademark.	**2006-10-24_64915_CORR_PHONE_LTANNER_MROBB_.pdf**	64,915
1	Regulatory	US	**10/20/2006**	Book 83	FDA Submission - IND	**Protocol Amendment. New Investigators. S-160**	**S-160**	64,915
1	Regulatory	US	**10/20/2006**	Book 83	FDA Correspondence - Email	L.Tanner/M.Robb - FDA contact report (e-mail) - Proposal for 4-month Safety Update to NDA, S-159	**2006-10-20_64915_CORR_EMAIL_LTANNER_MROBB_.pdf**	64,915
1	Regulatory	US	**10/16/2006**	Book 83	FDA Correspondence - Email	L.Tanner/M.Robb - FDA contact report (e-mail) that confirms that the word version of the PI needs to be submitted in the two-column format.	**2006-10-16_64915_CORR_EMAIL_LTANNER_MROBB_.pdf**	64,915
1	Regulatory	US	**10/13/2006**	Book 83	FDA Submission - IND	**Other: Proposal for 4-Month Safety Update. S-159**	**S-159**	64,915
1	Regulatory	US	**10/12/2006**	Book 83	FDA Correspondence - Email	L.Tanner/M.Rabb. Email with two attachments. Clarification on Format of PI; 1vs. 2 Column Format for the PI; Ambrisentan.	**2006-10-12_64915_CORR_EMAIL_LTANNER_MROBB_.pdf**	64,915
1	Regulatory	US	**10/10/2006**	Book 83	FDA Correspondence - Email	Email from T.Marshall to S. Goldie with the attachment - electronic Desk Copy of AMB S-157: New Commercial Drug Product Dissolution Method.	**2006-10-10_64915_CORR_EMAIL_TMARSHALL_SGOLDIE_.pdf**	64,915
1	Regulatory	US	**10/9/2006**	Book 83	FDA Submission - IND	**IND Safety Report. Initial and Follow-up Written Report. S-158**	**S-158**	64,915
1	Regulatory	US	**10/6/2006**	Book 83	FDA Submission - IND	**Other: CMC - Proposed Commercial Dissolution Method. S-157**	**S-157**	64,915
1	Regulatory	US	**10/4/2006**	Book 83	FDA Correspondence - Email	Email from M. Robb to L. Tanner. Subject: Pediatric exclusivity, Orphan Drugs; Ambrisentan - ND 22-081.	**2006-10-04_64915_CORR_EMAIL_LTANNER_MROBB_.pdf**	64,915

1	Regulatory	US	**10/4/2006**	Book 83	FDA Correspondence - Phone	M.Robb/L.Tanner. Purpose: Confirm location for providing the statement that ambrisentan is exempt from the requirement for submitting pediatric data in the NDA.	**2006-10-04_64915_CORR_PHONE_MROBB_LTANNER_.pdf**	64,915
1	Regulatory	US	**9/27/2006**	Book 83	FDA Correspondence - Phone	M.Robb/L.Tanner. Purpose: Confirm timing for the submission of NDA.	**2006-09-27_64915_CORR_PHONE_MROBB_LTANNER_.pdf**	64,915
1	Regulatory	US	**9/26/2006**	Book 82	FDA Submission - IND	**Protocol Amendment. New Investigators. S-156**	**S-156**	64,915
1	Regulatory	US	**9/12/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Initial and Follow-up Written Report. S-155**	**S-155**	64,915
1	Regulatory	US	**9/6/2006**	Book 82	FDA Submission - IND	**Protocol Amendment AMB-323. New Investigators. S-154**	**S-154**	64,915
1	Regulatory	US	**8/23/2006**	Book 82	FDA Correspondence - Letter - Meeting Minutes	Letter from S.Goldie/T.Marshall Meeting Minutes - Pre-NDA CMC meeting with FDA.	**2006-08-23_64915_CORR_MEETING_MINUTES.pdf**	64,915
1	Regulatory	US	**8/21/2006**	Book 82	FDA Correspondence - Email	Email from the FDA User Fee System	**2006-08-21_64915_CORR_EMAIL_USERFEESFDA_HISOKOSKI_.pdf**	64,915
1	Regulatory	US	**8/8/2006**	Book 82	FDA Correspondence - Phone	L.Tanner/M.Robb. Call at 2:30 PM. Purpose: Confirm Format of Annotating Prescribing Information.	**2006-08-08_64915_CORR_PHONE_MROBB_LTANNER_2.pdf**	64,915
1	Regulatory	US	**8/8/2006**	Book 82	FDA Correspondence - Phone	L.Tanner/M.Robb. Call at 8:30AM Purpose: Confirm format of annotating the prescribing information based on the new requirements.	**2006-08-08_64915_CORR_PHONE_MROBB_LTANNER_.pdf**	64,915
1	Regulatory	US	**7/26/2006**	Book 82	FDA Correspondence - Mating Minutes	T.Marshall. Myogen Pre-NDA CMC Meeting Minutes for July 26, 2006.	**2006-07-26_64915_CORR_MEETING_MINUTES.pdf**	64,915
1	Regulatory	US	**7/25/2006**	Book 82	FDA Submission - IND	**Protocol Amendment. New Investigators. S-153**	**S-153**	64,915
1	Regulatory	US	**7/24/2006**	Book 82	FDA Correspondence - Email	T.Marshall/S.Goldie. FDA Pre-meeting Responses to Myogen's Pre-NDA CMC Meeting Questions.	**2006-07-24_64915_CORR_EMAIL_TMARSHALL_SGOLDIE_1.pdf**	64,915
1	Regulatory	US	**7/24/2006**	Book 82	FDA Correspondence - Email	T.Marshall/S.Goldie. Pre-NDA CMC Meeting - Additional Attendees.	**2006-07-24_64915_CORR_EMAIL_TMARSHALL_SGOLDIE.pdf**	64,915
1	Regulatory	US	**7/17/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Safety Report. S-152**	**S-152**	64,915

1	Regulatory	US	**7/13/2006**	Book 82	FDA Correspondence - Phone	H.Isokoski/B.Friedman. NDA Number for Ambrisentan.	**2006-07-12_64915_CORR_PHONE_HISOKOSKI_BFRIEDMAN_.pdf**	64,915
1	Regulatory	US	**7/6/2006**	Book 82	FDA Correspondence - Email	L.CURRAN/ESUB/FDA. To clarify issues to which there is no apparent guidance.	**2006-07-06_64915_CORR_EMAIL_ESUB_LCURRAN.pdf**	64,915
1	Regulatory	US	**7/6/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Safety Report. S-151**	**S-151**	64,915
1	Regulatory	US	**6/30/2006**	Book 107-108	FDA Submission - IND	**Annual Report. S-150**	**S-150**	64,915
1	Regulatory	US	**6/28/2006**	Book 106	FDA Submission - IND	**Other. CMC Pre-NDA Information Package S-149**	**S-149**	64,915
1	Regulatory	US	**6/20/2006**	Book 82	FDA Submission - IND	**Information Amendment. Update to Investigator 1572 Forms. S-148**	**S-148**	64,915
1	Regulatory	US	**6/20/2006**	Book 82	FDA Correspondence - Phone	L.Tanner/M.Rabb. Feedback on proposed plan for submitting carcinogenicity data to the NDA (IND Serial No. 145).	**2006-06-20_64915_CORR_PHONE_MROBB_LTANNER_.pdf**	64,915
1	Regulatory	US	**6/20/2006**	Book 105	FDA Submission - IND	**Information Amendment. New Protocol and New Investigator. S-147**	**S-147**	64,915
1	Regulatory	US	**6/15/2006**	Book 100-104	FDA Submission - IND	**Information Amendment -Clinical CSRs AMB-105 and AMB-106. S-146**	**S-146**	64,915
1	Regulatory	US	**6/14/2006**	Book 82	FDA Correspondence - Phone	Phone. T.Marshall/S.Goldie regarding Pre-NDA CMC Meeting. Scheduling Submission of Pre-NDA CMC meeting information.	**2006-06-14_64915_CORR_PHONE_SGOLDIE_TMARSHALL.pdf**	64,915
1	Regulatory	US	**6/14/2006**	Book 82	FDA Correspondence - Email	Email from L.Tanner/M.Robb - Request for feedback: IND64,915 S-145.	**2006-06-14_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**6/14/2006**	Book 82	FDA Submission - IND	**Other. Request Feedback on Nonclinical NDA Format and Content. S-145**	**S-145**	64,915
1	Regulatory	US	**6/12/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Initial and Follow-up Written Report. S-144**	**S-144**	64,915
1	Regulatory	US	**6/2/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-143**	**S-143**	64,915
1	Regulatory	US	**6/1/2006**	Book 82	FDA Submission - IND	**Information Amendment. Update to Investigator 1572 Forms. S-142**	**S-142**	64,915

1	Regulatory	US	**5/26/2006**	Book 82	FDA Correspondence - Letter	Letter from S.Goldie/T.Marshall regarding Pre-NDA CMC meeting with FDA.	**2006-05-26_64915_CORR_LETTER_SGOLDIE_TMARSHALL.pdf**	64,915
1	Regulatory	US	**5/26/2006**	Book 82	FDA Correspondence - Fax	Fax from M.Robb/L.Tanner - Meeting Minutes from Pre-NDA meeting with FDA on May 19, 2006.	**2006-05-26_64915_CORR_FAX_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**5/26/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Follow-up to a Written Report. S-141**	**S-141**	64,915
1	Regulatory	US	**5/25/2006**	Book 82	FDA Correspondence - Email	S.Goldie/T.Marshall. Contract Information.	**2006-05-25_64915_CORR_EMAIL_TMARSHALL_SGOLDIE.pdf**	64,915
1	Regulatory	US	**5/25/2006**	Book 82	FDA Correspondence - Phone	Phone call - T.Marshall/S.Goldie regarding Pre-NDA CMC meeting request.	**2006-05-25_64915_CORR_PHONE_SGOLDIE_TMARSHALL.pdf**	64,915
1	Regulatory	US	**5/19/2006**	Book 82	FDA Correspondence - Phone	Phone call - T.Marshall/M.Robb regarding Pre-NDA CMC meeting request.	**2006-05-19_64915_CORR_PHONE_MROBB_TMARSHALL.pdf**	64,915
1	Regulatory	US	**5/19/2006**	Book 82	FDA Correspondence - Email	Email - T.Marshall/S.Goldie regarding Pre-NDA CMC meeting. IND Submission S-139 attached.	**006-05-19_64915_CORR_EMAIL_TMARSHALL_SGOLDIE.pdf**	64,915
1	Regulatory	US	**5/18/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-140**	**S-140**	64,915
1	Regulatory	US	**5/17/2006**	Book 82	FDA Correspondence - Email	Email - L.Tanner/M.Robb. To discuss comments and questions (pre-NDA meeting with FDA).	**2006-05-17_64915_CORR_EMAIL_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**5/17/2006**	Book 82	FDA Submission - IND	**Other. Type B Meeting Request: Pre-NDA CMC. S-139**	**S-139**	64,915
1	Regulatory	US	**5/8/2006**	Book 82	FDA Correspondence - Email	L.Tanner/M.Robb - Response to FDA comment (SN#138) regarding scoop and content of NDA.	**2006-05-08_64915_CORR_EMAIL_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**5/8/2006**	Book 82	FDA Submission - IND	**Other: Response to FDA Comments. S-138**	**S-138**	64,915
1	Regulatory	US	**5/5/2006**	Book 82	FDA Correspondence - Phone	Phone call - L.Tanner/M.Rabb to discuss status of written comments to questions in pre-NDA briefing document (IND Serial No.134)	**2006-05-05_64915_CORR_PHONE_MROBB_LTANNER_1.pdf**	64,915

1	Regulatory	US	**5/5/2006**	Book 82	FDA Correspondence - Phone	Phone call - L.Tanner/M.Rabb. Myogen response to Division comments on IND Serial No. 127; date of internal meeting; clarify FDA position on use of audio-visual aids.	**2006-05-05_64915_CORR_PHONE_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**5/4/2006**	Book 97-99	FDA Submission - IND	**Information Amendment. Pharmacology/Toxicology. S-137**	**S-137**	64,915
1	Regulatory	US	**4/27/2006**	Book 82	FDA Submission - IND	**Protocol Amendment. New Investigators Update. S-136**	**S-136**	64,915
1	Regulatory	US	**4/27/2006**	Book 82	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-135**	**S-135**	64,915
1	Regulatory	US	**4/21/2006**	Book 96	FDA Submission - IND	**Other: Pre-NDA Briefing Document. S-134**	**S-134**	64,915
1	Regulatory	US	**4/21/2006**	Book 82	FDA Correspondence - Multiple	Purpose: To test system upgrade and functionality in advance of actual Ambrisentan eCTD.	**2006-04-21_64915_CORR_MULTIPLE_LCURRAN_CDER_ESUB.pdf**	64,915
1	Regulatory	US	**4/20/2006**	Book 82	FDA Correspondence - Letter	The response to the questions regarding the NDA that was submitted in IND Serial No. 127	**2006-04-20_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	**4/19/2006**	Book 92-95	FDA Submission - IND	**Information Amendment. Pharmacology/Toxicology. S-133**	**S-133**	64,915
1	Regulatory	US	**4/19/2006**	Book 81	FDA Submission - IND	**Other: Population Pharmacokinetic (PK) Data Analysis Plan (DAP) Amendment. S-132**	**S-132**	64,915
1	Regulatory	US	**4/17/2006**	Book 81	FDA Correspondence - Phone	Phone call L.Tanner/M.Robb regarding status of FDA responses to questions relative to the NDA submitted in S-127	**2006-04-17_64915_CORR_PHONE_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**4/11/2006**	Book 81	FDA Correspondence - Email	Email with the Word Attachment - L.Tanner/M.Robb regarding status of FDA responses to questions relative to the NDA submitted in S-127	**2006-04-11_64915_CORR_EMAIL_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**4/11/2006**	Book 81	FDA Correspondence - Phone	Phone call L.Tanner/M.Robb regarding status of FDA responses to questions relative to the NDA submitted in S-127	**2006-04-11_64915_CORR_PHONE_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**4/5/2006**	Book 81	FDA Correspondence - Phone	Phone call - L.Tanner/N.Beasley regarding analysis of pharmacokinetic parameters vs. QTc interval assessments.	**2006-04-05_64915_CORR_PHONE_LTANNER_NBEASLEY.pdf**	64,915

1	Regulatory	US	**4/5/2006**	Book 91	FDA Submission - IND	**Information Amendment. Pharmacology/Toxicology. S-131**	**S-131**	64,915
1	Regulatory	US	**3/29/2006**	Book 81	FDA Submission - IND	**Protocol Amendment. New Investigators and Investigator Update. S-130**	**S-130**	64,915
1	Regulatory	US	**3/24/2006**	Book 81	FDA Submission - IND	**Information Amendment Pharmacology/Toxicology. S-129**	**S-129**	64,915
1	Regulatory	US	**3/23/2006**	Book 81	FDA Correspondence - Phone	Phone call, L.Tanner/M.Robb - Clarification of FDA participants for pre-NDA meeting scheduled May 19, 2006.	**2006-03-23_64915_CORR_PHONE_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**3/23/2006**	Book 89-90	FDA Submission - IND	**Information Amendment. Pharmacology/Toxicology. S-128**	**S-128**	64,915
1	Regulatory	US	**3/23/2006**	Book 81	FDA Correspondence - Email	E-mail from L.Tanner /M.Robb to obtain feedback from the statisticians on how to address their recommendations regarding the methodology used in the DAPs for the individual Phase 3 studies AMB-320 and AMB-321.	**2006-03-23_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**3/21/2006**	Book 81	FDA Correspondence - Phone	Phone call, L.Tanner/M.Robb - Clarification of FDA participants for pre-NDA meeting scheduled May 19, 2006.	**2006-03-21_64915_CORR_PHONE_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**3/20/2006**	Book 81	FDA Correspondence - Fax	Fax from M.Robb/L.Tanner regarding Pre-NDA meeting conformation with FDA on May 19, 2006.	**2006-03-20_64915_CORR_FAX_MROBB_LTANNER.pdf**	64,915
1	Regulatory	US	**3/16/2006**	Book 81	FDA Correspondence - Letter	Letter from N.Stockridge/L.Tanner - Comments (Clinical Pharmacology and Biopharmaceutics) on AMB submission.	**2006-03-16_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	**3/15/2006**	Book 81	FDA Submission - IND	**Other. Requirements and Format of NDA. S-127**	**S-127**	64,915
1	Regulatory	US	**3/15/2006**	Book 81	FDA Correspondence - Email	L.Tanner/M.Robb - Email regarding IND 64,915; Serial No. 127; Requirements and Format of NDA.	**2006-03-15_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**3/14/2006**	Book 81	FDA Correspondence - Letter	Letter from N.Stockridge/L.Tanner with the comments on AMB submission.	**2006-03-14_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	**3/14/2006**	Book 81	FDA Correspondence - Email	L.Curran/K.Edmunds - Email regarding Pilot Submission.	**2006-03-14_64915_CORR_EMAIL_LCURRAN_KEDMUNDS.pdf**	64,915

1	Regulatory	US	3/10/2006	Book 81	FDA Correspondence - Phone call	L.Tanner/M.Robb phone call regarding feedback on : submission of the rat carcinogenicity, acceptability of cross-reference to NDA in the IND Annual Report, notification of submission with questions on scope, format and date of pre-NDA meeting.	**2006-03-10_63412_CORR_PHONE_LTANNER_MROBB_.pdf**	64,915
1	Regulatory	US	3/8/2006	Book 81	FDA Submission - IND	**Other: Type B Meeting Request: Pre-NDA. S-126**	**S-126**	64,915
1	Regulatory	US	3/2/2006	Book 81	FDA Submission - IND	**Protocol Amendment. New investigators and 1572 Update. S-125**	**S-125**	64,915
1	Regulatory	US	3/2/2006	Book 81	FDA Submission - IND	**IND Safety Report. Follow-up to a Fax Report: 52597. S-124**	**S-124**	64,915
1	Regulatory	US	2/27/2006	Book 81	FDA Correspondence - Phone call/Fax	L.Curran called M.Robb to inform her that he would be faxing a 7-Day Safety Report. Faxed 7-Day Safety Report.	**2006-02-27_64915_CORR_PHONE_FAX_LCURRAN_MROBB.pdf**	64,915
1	Regulatory	US	2/21/2006	Book 81	FDA Submission - IND	**Other: Response to the IND correspondence. S-123**	**S-123**	64,915
1	Regulatory	US	2/15/2006	Book 81	FDA Correspondence - Letter	Letter from N.Stockbridge to L. Tanner regarding FDA approval for fast track designation.	**2006-02-15_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	2/9/2006	Book 88	FDA Submission - IND	**Other. Request for Fast Track Designation. S-122**	**S-122**	64,915
1	Regulatory	US	2/8/2006	Book 81	FDA Correspondence - Letter	Letter from N.Stockbridge to L. Tanner regarding Myogen request for additional clarification to a letter dated 22 December 2005 regarding the changes to the statistical analysis plans that was reflected in the protocol amendments to AMB-320 and AMB-321.	**2006-02-08_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	2/8/2006	Book 81	FDA Correspondence - Phone call	Phone call L.Tanner/M.Robb. Confirm whether the popPK DAP has been reviewed and whether Division comments will be forthcoming.	**2006-02-08_63412_CORR_PHONE_LTANNER_MROBB_.pdf**	64,915
1	Regulatory	US	1/30/2006	Book 81	FDA Correspondence - Phone call	Phone call - L.Tanner/B.N.Beasley regarding status of Clinical QT/QTc Study AMB-104	**2006-01-30_64915_CORR_PHONE_LTANNER_BNBEASLEY.pdf**	64,915

1	Regulatory	US	**1/27/2006**	Book 81	FDA Submission - IND	**IND Safety Report. Initial Written Report: 51629. Follow-Up to a Written Report: 52559. S-121**	**S-121**	64,915
1	Regulatory	US	**1/26/2006**	Book 87	FDA Submission - IND	**Protocol Amendment. Change in Protocol AMB-104. S-120**	**S-120**	64,915
1	Regulatory	US	**1/25/2006**	Book 81	FDA Submission - IND	**Protocol Amendment. New investigators and 1572 Update. S-119**	**S-119**	64,915
1	Regulatory	US	**1/24/2006**	Book 86	FDA Submission - IND	**Protocol Amendment. Change in Protocol AMB-222. S-118**	**S-118**	64,915
1	Regulatory	US	**1/23/2006**	Book 81	FDA Correspondence - Phone call	Phone call L.Tanner/M.Robb. Feedback on submitting additional documentation to support changes in the revised Protocol AMB-222 that was submitted in Serial No. 115	**2006-01-23_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**1/23/2006**	Book 85	FDA Submission - IND	**Protocol Amendment. Change in Protocol AMB-107. S-117**	**S-117**	64,915
1	Regulatory	US	**1/19/2006**	Book 81	FDA Correspondence - Phone call	Phone call - L.Tanner/L.Velazquez regarding feedback on Bioequivalence Protocol AMB-103 submitted on 12/19/2005 S-108.	**2006-01-19_64915_CORR_PHONE_LTANNER_LVELAZQUEZ.pdf**	64,915
1	Regulatory	US	**1/16/2006**	Book 81	FDA Submission - IND	**IND Safety Report. Follow-up to a written Report: 52566. S-116**	**S-116**	64,915
1	Regulatory	US	**1/13/2006**	Book 84	FDA Submission - IND	**Protocol Amendment. Change in Protocol. S-115**	**S-115**	64,915
1	Regulatory	US	**1/10/2006**	Book 81	FDA Correspondence - Phone call	Phone call L.Tanner/M.Robb. Follow-up on clarification on FDA statistical comments to protocol amendments for AMB-320 and AMB-321.	**2006-01-10_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**1/9/2006**	Book 81	FDA Submission - IND	**IND Safety Report. Follow-up to a written Report: 51627. S-114**	**S-114**	64,915
1	Regulatory	US	**1/5/2006**	Book 81	FDA Correspondence - Email	Email - M.Robb/L.Tanner regarding IND 64,915 Letairis trade name - Response to Questions.	**2006-01-05_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**1/4/2006**	Book 81	FDA Submission - IND	**IND Safety Report. Initial Written Report. S-113**	**S-113**	64,915

1	Regulatory	US	12/28/2005	Book 52	FDA Correspondence - Email	Email - M.Robb/L.Tanner regarding IND 64,915 Letairis trade name.	2005-12-28_64915_CORR_EMAIL_LTANNER_MROBB.pdf	64,915
1	Regulatory	US	12/27/2005	Book 52	FDA Correspondence - Fax	The FDA minutes for the Type C meeting scheduled as a teleconference on 15 December 2005 to discuss the PK/PD development plan. Attached are Internal (Myogen) Minutes for the same meeting.	2005-12-27_64915_CORR_FAX_MTG_MINUTES_LTANNER_MROBB.pdf	64,915
1	Regulatory	US	12/22/2005	Book 52	FDA Correspondence - Letter	Letter from N. Stockbridge to L.Tanner regarding comments on ARIES-2 DAP.	2005-12-22_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf	64,915
1	Regulatory	US	12/21/2005	Book 52	FDA Correspondence - Phone call	Phone call on 12-20-2005 and 12-21-2005 L.Tanner/M.Robb. Intent to submit application for fast track designation.	2005-12-21_64915_CORR_PHONE_LTANNER_MROBB.pdf	64,915
1	Regulatory	US	12/21/2005	Book 52	FDA Submission - IND	**IND Safety Report. Initial Written Report: 51627. S-112**	S-112	64,915
1	Regulatory	US	12/21/2005	Book 52	FDA Submission - IND	**IND Safety Report. Initial Written Report: 52559. S-111**	S-111	64,915
1	Regulatory	US	12/20/2005	Book 80	FDA Submission - IND	**Protocol Amendment. New Protocol (AMB-107) and New Investigator. S-110**	S-110	64,915
1	Regulatory	US	12/19/2005	Book 52	FDA Correspondence - Email	ECG measurements on Baseline and Treatment Days in Protocol AMB-104.	2005-12-19_64915_CORR_EMAIL_LTANNER_MROBB.pdf	64,915
1	Regulatory	US	12/19/2005	Book 52	FDA Submission - IND	**IND Safety Report. Initial Written Report: 52555. S-109**	S-109	64,915
1	Regulatory	US	12/19/2005	Book 79	FDA Submission - IND	**Protocol Amendment. New Protocol (AMB-103) and New Investigators. S-108**	S-108	64,915
1	Regulatory	US	12/19/2005	Book 52	FDA Correspondence - Phone call	Phone call. T.Marshall/M.Robb. Feedback from Ambrisentan Chemistry Reviewer for Drug Substance and Drug Product IND Amendments.	2005-12-19_64915_CORR_PHONE_TMARSHALL_MROBB.pdf	64,915
1	Regulatory	US	12/16/2005	Book 52	FDA Correspondence - Phone call	Phone call. T.Marshall/M.Robb. Request Feedback from Ambrisentan Chemistry Reviewer for Drug Product Update.	2005-12-16_64915_CORR_PHONE_TMARSHALL_MROBB.pdf	64,915

1	Regulatory	US	**12/15/2005**	Book 52	FDA Correspondence - Email	Email - L.Tanner/M.Robb. Subject: List of Myogen Participants Type C Meeting 12/15/2005.	**2005-12-15_64915_CORR_EMAIL_LTANNER_MROBB_1.pdf**	64,915
1	Regulatory	US	**12/15/2005**	Book 52	FDA Correspondence - Email	Email - L.Tanner/M.Robb. Subject: Clarification on Medical Review Comments QT/QTc Protocol AMB-104.	**2005-12-15_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**12/14/2005**	Book 52	FDA Correspondence - Email	Email - L.Tanner/M.Robb. Subject: Slides Top Line Results Phase 3 Study AMB-321; IND 64,915 Ambrisentan.	**2005-12-14_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**12/14/2005**	Book 52	FDA Correspondence - Phone call	Phone call from L. Tanner to M. Robb. Subject: Type C teleconference meeting scheduled 12/15/05; QT/QTc Study (AMB-104)	**2005-12-14_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**12/13/2005**	Book 52	FDA Correspondence - Email	Email - L. Tanner/M.Robb. Conformation of FDA Participants Teleconference - 12/15/2005.	**2005-12-13_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**12/12/2005**	Book 52	FDA Correspondence - Phone call	Phone call (on 12/09/05 and 12/12/05) from L. Tanner to M. Robb. Subject: Clarify FDA participations Type C teleconference meeting scheduled 12/15/2005.	**2005-12-12_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**12/6/2005**	Book 52	FDA Correspondence - Email	Email - L.Tanner/M.Robb. Subject: Ambrisentan Type C Meeting: Myogen Participants and Teleconference Instruction.	**2005-12-06_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**12/1/2005**	Book 52	FDA Correspondence - Email	Email - L.Tanner/M.Robb. Subject: Electronic Copy of S-106 - Analysis Plan for Population Pharmacokinetic Modeling.	**2005-12-01_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**12/1/2005**	Book 73-78	FDA Submission - IND	**Information Amendment. Clinical Study Report EE002. S-107**	**S-107**	64,915
1	Regulatory	US	**12/1/2005**	Book 52	FDA Correspondence - Phone call	Phone call - L.Tanner/M.Robb. Purpose: To confirm receipt of desk copies of PK/PD briefing package for the teleconference meeting scheduled 15 December 2005 and update on IND submissions this week.	**2005-12-01_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**11/30/2005**	Book 52	FDA Submission - IND	**Other: Data Analysis Plan for Population Pharmacokinetic Modeling. S-106**	**S-106**	64,915

1	Regulatory	US	**11/30/2005**	Book 72	FDA Submission - IND	**Other: Briefing Document for Type c Meeting. S-105**	**S-105**	64,915
1	Regulatory	US	**11/30/2005**	Book 71	FDA Submission - IND	**Protocol. New Protocol and New Investigator. S-104**	**S-104**	64,915
1	Regulatory	US	**11/30/2005**	Book 70	FDA Submission - IND	**Other: Data Analysis Plans. S-103**	**S-103**	64,915
1	Regulatory	US	**11/29/2005**	Book 69	FDA Submission - IND	**Other: Data Analysis Plans. S-102**	**S-102**	64,915
1	Regulatory	US	**11/29/2005**	Book 65-68	FDA Submission - IND	**Information Amendment. Pharmacology/Toxicology. S-101**	**S-101**	64,915
1	Regulatory	US	**11/28/2005**	Book 52	FDA Correspondence - Phone call	Phone call - L.Tanner/M.Robb. Myogen response to FDA comments on the QT/QTc study design (Serial No. 096)	**2005-11-28_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**11/28/2005**	Book 64	FDA Submission - IND	**Other. Data Analysis Plan. S-100**	**S-100**	64,915
1	Regulatory	US	**11/23/2005**	Book 63	FDA Submission - IND	**Protocol Amendment. New Investigators. S-099**	**S-099**	64,915
1	Regulatory	US	**11/16/2005**	Book 52	FDA Correspondence - Phone call	Phone call - L.Tanner/M.Robb. Purpose: Instruction for shipping PK/PD package for the teleconference meeting scheduled 12/15/2005.	**2005-11-16_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**11/14/2005**	Book 52	FDA Correspondence - Phone call	Phone call - L.Tanner/M.Robb. Purpose: To confirm timing of submitting the PK/PD briefing package for the teleconference meeting scheduled 15 December 2005.	**2005-11-14_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**11/11/2005**	Book 62	FDA Submission - IND	**Protocol Amendment. Change in Protocol. Information Amendment Clinical. S-098**	**S-098**	64,915
1	Regulatory	US	**11/11/2005**	Book 52	FDA Submission - IND	**Information Amendment. Pharmacology/Toxicology 2-Year Rat and Mouse Carcinogenicity Studies. S-097**	**S-097**	64,915
1	Regulatory	US	**11/10/2005**	Book 52	FDA Correspondence - Phone call	Phone call - L.Tanner/W.Link on 11/10/05 and 11/09/05 regarding 2 year carcinogenicity (CAC) studies in mice and rats.	**2005-11-10_64915_CORR_PHONE_LTANNER_WLINK.pdf**	64,915

1	Regulatory	US	**11/9/2005**	Book 52	FDA Correspondence - Phone call	Phone call - L.Tanner/M.Robb on 11/08/05 and 11/09/05 regarding 2 year carcinogenicity (CAC) studies in mice and rats. Arrange teleconference with Dr. William Link to provide survival update on CAC studies.	**2005-11-09_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**11/7/2005**	Book 52	FDA Submission - IND	**Other: Response to FDA Comments on QT/QTc Study Design. S-096**	**S-096**	64,915
1	Regulatory	US	**11/4/2005**	Book 61	FDA Submission - IND	**Protocol. New Protocol and New Investigator. S-095**	**S-095**	64,915
1	Regulatory	US	**11/4/2005**	Book 52	FDA Submission - IND	**Other: Trademark Evaluation. S-094**	**S-094**	64,915
1	Regulatory	US	**10/24/2005**	Book 52	FDA Correspondence - Email	Email from R. Fortney to L. Weissberger regarding minutes from October 19, 2005 teleconference.	**2005-10-24_64915_CORR_EMAIL_RFORTNEY_LWEISSBERGER.pdf**	64,915
1	Regulatory	US	**10/21/2005**	Book 60	FDA Submission - IND	**Protocol Amendment: New Investigators. Other: Revisions to FDA Forms 1572. S-093**	**S-093**	64,915
1	Regulatory	US	**10/20/2005**	Book 52	FDA Correspondence - Phone call	Phone call form L. Weissberger to M. Robb. Subject: QT/QTc study - comments on study design submitted for both darusentan (Serial No. 076) and ambrisentan (Serial No. 086)	**2005-10-20_64915_CORR_PHONE_LWEISSBEGER_MROBB.pdf**	64,915
1	Regulatory	US	**10/19/2005**	Book 52	FDA Correspondence - Letter	Letter from R. Fortney to L. Weissberger. Teleconference Minutes from FDA and Internal Minutes - October 19, 2005.	**2005-10-19_64915_CORR_LETTER_RFORTNEY_LWEISSBERGER.pdf**	64,915
1	Regulatory	US	**10/19/2005**	Book 52	FDA Correspondence - Email	Email from L. Tanner to R. Fortney regarding teleconference on October 19, 2005.	**2005-10-19_64915_CORR_EMAIL_RFORTNEY_LTANNER.pdf**	64,915
1	Regulatory	US	**10/18/2005**	Book 52	FDA Submission - IND	**Protocol. New Protocol and New Investigator. S-092**	**S-092**	64,915
1	Regulatory	US	**10/13/2005**	Book 52	FDA Correspondence - Email	Email from R. Fortney to L. Weissberger regarding FDA letter with comments on QT/QTc Study.	**2005-10-13_64915_CORR_EMAIL_RFORTNEY_LWEISSBERGER.pdf**	64,915
1	Regulatory	US	**10/12/2005**	Book 52	FDA Correspondence - Letter	Letter from N. Stockbridge to L. Weissberger. Comments on QT/QTc study proposal for Ambrisentan.	**2005-10-12_64915_CORR_LETTER_NSTOCKBRIDGE_LWEISSBERGER.pdf**	64,915

1	Regulatory	US	**10/12/2005**	Book 52	FDA Correspondence - Phone call	Phone call. L. Tanner/R. Fortney. Subject: Teleconference DAP; S-084	**2005-10-12_64915_CORR_PHONE_LTANNER_RFORTNEY.pdf**	64,915
1	Regulatory	US	**10/12/2005**	Book 52	FDA Correspondence - Email	Email from L. Tanner to R. Fortney regarding Teleconference on 10/19/2005, additional participant.	**2005-10-12_64915_CORR_EMAIL_RFORTNEY_LTANNER.pdf**	64,915
1	Regulatory	US	**10/11/2005**	Book 52	FDA Correspondence - Phone call	Phone call. L. Tanner/R. Fortney. L. Tanner called R. Fortney on 10/06/05, 10/10/05 and 10/11/05. Subject: Teleconference DAP; S-084	**2005-10-11_64915_CORR_PHONE_LTANNER_RFORTNEY.pdf**	64,915
1	Regulatory	US	**10/11/2005**	Book 52	FDA Correspondence - Email	Email from R. Fortney to L. Weissberger regarding QT Study Comments.	**2005-10-11_64915_CORR_EMAIL_RFORTNEY_LWEISSBERGER.pdf**	64,915
1	Regulatory	US	**10/5/2005**	Book 52	FDA Correspondence - Phone call	Phone call. L. Tanner/R. Fortney. Subject: Reschedule Type C Meeting; S-087	**2005-10-05_64915_CORR_PHONE_LTANNER_RFORTNEY.pdf**	64,915
1	Regulatory	US	**10/4/2005**	Book 59	FDA Submission - IND	**Information Amendment. Chemistry, Manufacturing, and Controls. S-091**	**S-091**	64,915
1	Regulatory	US	**10/4/2005**	Book 52	FDA Submission - IND	**IND Safety Report: Follow-up to a Written Report. S-090**	**S-090**	64,915
1	Regulatory	US	**10/4/2005**	Book 52	FDA Correspondence - Phone call	Phone call. L. Tanner/R. Fortney. Subject: Intention to Cancel or Re-schedule Type C Meeting; Serial No. 087	**2005-10-04_64915_CORR_PHONE_LTANNER_RFORTNEY.pdf**	64,915
1	Regulatory	US	**9/28/2005**	Book 52	FDA Correspondence - Letter	Letter from N. Stockbridge to L. Tanner regarding FDA Division comments on the Data Analysis Plan for AMB-321.	**2005-09-28_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	**9/26/2005**	Book 58	FDA Submission - IND	**Protocol Amendment: New Investigators: Gabbay, Channick, Frost, Waxman, Sulica, Taichman, Olschewski, Souza, Pulido, Rivera, Swisher, Booth, Ross, White. S-089**	**S-089**	64,915
1	Regulatory	US	**9/21/2005**	Book 52	FDA Correspondence - Fax	Fax from M. Robb to L. Tanner. Subject: Conformation of 11/08/2005 Teleconference.	**2005-09-21_64915_CORR_FAX_MROBB_LTANNER.pdf**	64,915

1	Regulatory	US	**9/20/2005**	Book 52	FDA Correspondence - Phone call	Phone call L.Tanner/M.Robb. Finalize Date/Time of Type C Teleconference/Meeting. (Serial No.087); Status of DAP (Serial No. 084)	**2005-09-20_64915_CORR_PHONE_LTANNER_ROBBM.pdf**	64,915
1	Regulatory	US	**9/19/2005**	Book 52	FDA Correspondence - Phone call	Phone call T. Marshall/M.Robb. Subject: Follow-up to determine if Chemistry reviewer has any concerns regarding the drug substance IND update: IND 64,915, Serial No. 083, 4 Aug 05.	**2005-09-19_64915_CORR_PHONE_TMARSHALL_MROBB.pdf**	64,915
1	Regulatory	US	**9/19/2005**	Book 52	FDA Correspondence - Phone call	Phone call L.Tanner/M.Robb. Finalize Date/Time of Type C Teleconference/Meeting. (Serial No.087); Status of DAP (Serial No. 084)	**2005-09-19_64915_CORR_PHONE_LTANNER_ROBBM.pdf**	64,915
1	Regulatory	US	**9/15/2005**	Book 52	FDA Correspondence - Letter	Letter from N. Stockbridge to L. Tanner. Conformation that Food Effect Study Does not Need to be Repeated	**2005-09-15_64915_CORR_LETTER_NSTOCKBRIDGE_LTANNER.pdf**	64,915
1	Regulatory	US	**9/15/2005**	Book 52	FDA Submission - IND	**Information Amendment. Pharmacology/Toxicology 2-year Rat and Mouse Carcinogenicity Studies. S-088**	**S-088**	64,915
1	Regulatory	US	**9/15/2005**	Book 52	FDA Correspondence - Phone call	Phone called (1:30 p.m.) from L. Tanner to M. Robb regarding proposed Date for Type C Meeting PK/PD.	**2005-09-15_64915_CORR_PHONE_LTANNER_ROBBM.pdf**	64,915
1	Regulatory	US	**9/15/2005**	Book 52	FDA Correspondence - Phone call	Phone called (10:00 a.m.) from M. Robb to L. Tanner regarding proposed Date for Type C Meeting PK/PD.	**2005-09-15_64915_CORR_PHONE_LTANNER_ROBBM_2.pdf**	64,915
1	Regulatory	US	**9/12/2005**	Book 52	FDA Correspondence - Email	Email from L. Tanner to M.Robb regarding a Type C Meeting Request. S-087. Submission included.	**2005-09-12_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**9/12/2005**	Book 52	FDA Submission - IND	**Other: Type C Meeting Request, Development Plan for Biopharmaceutics and Clinical Pharmacology. S-087**	**S-087**	64,915
1	Regulatory	US	**9/7/2005**	Book 52	FDA Submission - IND	**Other: Request for FDA Review of QT/QTc Study Proposal. S-086**	**S-086**	64,915

1	Regulatory	US	9/7/2005	Book 52	FDA Correspondence - Phone call	Phone call. L.Tanner/M.Robb. Subject: request to Submit QT/QTc Study Proposal to IND.	2005-09-07_64915_CORR_PHONE_MROBB_LTANNER.pdf	64,915
1	Regulatory	US	8/31/2005	Book 52	FDA Correspondence - Email	Email from L.Weissberger to M.Robb regarding a summary of the QT/QTC evaluation proposing for Ambrisentan (64,915) and Darusentan (59,669).	2005-08-31_64915_CORR_EMAIL_WEISSBERGERL_ROBBM.pdf	64,915
1	Regulatory	US	8/25/2005	Book 52	FDA Submission - IND	**IND Safety Reports. S-085**	S-085	64,915
1	Regulatory	US	8/24/2005	Book 52	FDA Correspondence - Phone call	Phone call. M. Robb/L. Tanner. Subject: FDA Decision that Food Effect Study Does not Need to Be Repeated	2005-08-24_64915_CORR_PHONE_MROBB_LTANNER.pdf	64,915
1	Regulatory	US	8/23/2005	Book 52	FDA Correspondence - Phone call	Phone call from M. Robb to L. Tanner. Subject: Clarify 7-day SAE Process for IND 63,412; Confirm FDA receipt of PDF file for Serial No. 084 (IND 64,915); Status of Serial No. 082 Food Effect (64, 915); Potential meeting PK/PD development plan (IND 64,915)	2005-08-23_64915_CORR_PHONE_MROBB_LTANNER.pdf	64,915
1	Regulatory	US	8/22/2005	Book 52	FDA Submission - IND	**Other: Data Analysis Plan (AMB-321) for FDA Feedback. S-084**	S-084	64,915
1	Regulatory	US	8/22/2005	Book 52	FDA Correspondence - Phone call	Phone call from L. Tanner to M. Robb. Subject: Clarify 7-day SAE Process; Status of Serial No. 082 Food Effect; Notification of DAP Submission.	2005-08-22_64915_CORR_PHONE_LTANNER_MROBB.pdf	64,915
1	Regulatory	US	8/22/2005	Book 52	FDA Correspondence - Fax	Fax from L. Tanner to M. Robb. Subject: 7 Day Safety Report - Initial Manufacturer's Report No. 52505.	2005-08-22_64915_CORR_FAX_LTANNER_MROBB.pdf	64,915
1	Regulatory	US	8/19/2005	Book 52	FDA Correspondence - Phone call	Phone call. From M. Cooper to T. Marshall. Subject: Division feedback on ambrisentan starting materials (IND 64,915, Serial No. 083)	2005-08-19_64915_CORR_PHONE_MCOOPER_TMARSHALL.pdf	64,915
1	Regulatory	US	8/19/2005	Book 52	FDA Correspondence - Phone call	Phone call. From T. Marshall to M. Robb. On 8/18/2005 T. Marshall left voice message and on 8/19/2005 phoned M. Robb. Subject: Follow-up on requested feedback on starting materials from IND 64,915, Serial No. 083 dated 08/04/2005.	2005-08-19_64915_CORR_PHONE_TMARSHALL_MROBB.pdf	64,915

1	Regulatory	US	**8/4/2005**	Book 57	FDA Submission - IND	**Information Amendment: Chemistry, Manufacturing and Controls. S-083**	**S-083**	64,915
1	Regulatory	US	**8/4/2005**	Book 52	FDA Correspondence - Phone call	Phone call from L.Tanner to M.Robb. Subject: Confirm submission of S-082 Formulations Food/Effect.	**2005-08-04_64915_CORR_PHONE_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**8/4/2005**	Book 52	FDA Correspondence - Phone call	Phone call from T. Marshall to M.Robb. Left phone message. Subject: Informed Project Manager of Drug Substance CMC Information Amendment and Requested Feedback on Starting Materials.	**2005-08-04_64915_CORR_PHONE_TMARSHALL_MROBB.pdf**	64,915
1	Regulatory	US	**8/4/2005**	Book 52	FDA Correspondence - Email	Email from L. Tanner to M.Robb regarding submission S-082. Submission included.	**2005-08-04_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**8/3/2005**	Book 52	FDA Submission - IND	**Response To FDA Request For Information. S-082**	**S-082**	64,915
1	Regulatory	US	**7/26/2005**	Book 56	FDA Submission - IND	**Protocol Amendment. New Investigators.S-081 Keogh, Noordegraaf, Jennings, Murali, Schilz, Campos, Chatkin, Arakaki, Cardozo, Meyer, Kopisa, Hassoun, Feldman. S-081**	**S-081**	64,915
1	Regulatory	US	**6/30/2005**	Book 51	FDA Submission - IND	**Protocol Amendment. Annual Report. S-080**	**S-080**	64,915
1	Regulatory	US	**6/20/2005**	Book 51	FDA Submission - IND	**Protocol Amendment: New Investigators. Badesch, Foley, McGoon, Hassoun, Oudiz. Other: Revisions to FDA Form 1572. S-079**	**S-079**	64,915
1	Regulatory	US	**5/24/2005**	Book 51	FDA Submission - IND	**General Correspondence: Converting ARIES-2 Study Sites to ARIES-1. S-078**	**S-078**	64,915
1	Regulatory	US	**5/23/2005**	Book 51	FDA Submission - IND	**Protocol Amendment: New Investigators. Baratz, Barst, Fairman, Garcia, Mandel, Oudiz, Test. S-077**	**S-077**	64,915
1	Regulatory	US	**5/6/2005**	Book 51	FDA Correspondence - Phone call	Phone call. L.Weissberger/M.Robb. Subject: Follow-up on requirement for food effects study.	**2005-05-06_64915_CORR_PHONE_LWEISSBERGER_MROBB.pdf**	64,915

1	Regulatory	US	**5/3/2005**	Book 51	FDA Correspondence - Phone call	Phone call. L.Weissberger/M.Robb. Subject: Clarify message from Dr. Velazquez.	**2005-05-03_64915_CORR_PHONE_LWEISSBERGER_MROBB.pdf**	64,915
1	Regulatory	US	**5/2/2005**	Book 51	FDA Correspondence - Phone call	Phone call. L.Weissberger/L.Velazquez. Subject: Protocol AMB-222.	**2005-05-02_64915_CORR_PHONE_LWEISSBERGER_LVELAZQUEZ.pdf**	64,915
1	Regulatory	US	**4/29/2005**	Book 51	FDA Correspondence - Email	Email/M.Robb/L.Weissberger - 2-Year Rat and Mouse Bioassays.	**2005-04-29_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**4/27/2005**	Book 51	FDA Submission - IND	**Protocol Amendment: New Investigators. S-076 Kilinger, Hurewitz, Feldman, Arfaei, Nikolaevich. S-076**	**S-076**	64,915
1	Regulatory	US	**4/25/2005**	Book 51	FDA Correspondence - Phone call	Phone call. L.Weissberger/T.Link. FDA Response to our proposal for carcinogenicity studies.	**2005-04-25_64915_CORR_PHONE_LWEISSBERGER_WLINK.pdf**	64,915
1	Regulatory	US	**4/22/2005**	Book 51	FDA Correspondence - Phone call	Call to discuss 2-yr. Carcinogenicity studies.	**2005-04-22_64915_CORR_PHONE_LWEISS**	64,915
1	Regulatory	US	**4/12/2005**	Book 51	FDA Submission - IND	**Protocol Amendment: Change in Protocol. S-075**	**S-075**	64,915
1	Regulatory	US	**4/5/2005**	Book 53-55	FDA Submission - IND	**Vol. 1 - 3 -Response to FDA Request for Information. S-074**	**S-074**	64,915
1	Regulatory	US	**4/1/2005**	Book 51	FDA Correspondence - Email	Email/M.Robb/L.Weissberger - Response to FDA Request for Information	**2005-04-01_64915_CORR_EMAIL_LTANNER_MROBB.pdf**	64,915
1	Regulatory	US	**3/31/2005**	Book 50	FDA Submission - IND	**Protocol Amendment - L. Weissberger. New Investigator, Test, Noordegraaf, Kovalenko, Zagolin, Revisions to FDA Forms 1572. S-073**	**S-073**	64,915
		US	**3/28/2005**	Book 50	FDA Correspondence - Fax	Response to a request from FDA, and follow-up	**2005-03-28_64915_CORR_FAX_JFLIARD_NBEASLEY.pdf**	64,915
1	Regulatory	US	**3/24/2005**	Book 50	FDA Submission - IND	**Follow-up to a written Report. S-072**	**S-072**	64,915
1	Regulatory	US	**3/16/2005**	Book 50	FDA Correspondence - Letter	Stockbridge, N., Letter: Response to S 068 - Protocol Submission	**2005-03-16_64915_CORR_LETTER_MROBB_LWEISSBERGER.pdf**	64,915

1	Regulatory	US	3/9/2005	Book 50	FDA Submission - IND	L.Weissberger. Information Amendment. Pharmacology/Toxicology 2 year Rat and Mouse Carcinogenicity Studies. S-071	S-071	64,915
1	Regulatory	US	3/4/2005	Book 50	FDA Submission - IND	L. Weissberger. Protocol Amendment: New Investigators, Hassoun, Tereshchenko, Chakinala. S-070	S-070	64,915
1	Regulatory	US	2/18/2005	Book 50	FDA Submission - IND	L. Weissberger. General Correspondence. S-069	S-069	64,915
1	Regulatory	US	2/16/2005	Book 50	FDA Correspondence - Phone call	FDA Contact Report - Telephone. M.Robb/L.Weissberger. Subject: Existing "Food Effect" Study.	2005-02-16_64915_CORR_PHONE_LWEISSBERGER_MROBB.pdf	64,915
1	Regulatory	US	2/15/2005	Book 50	FDA Submission - IND	L.Weissberger. New Protocol: AMB-222. S-068	S-068	64,915
1	Regulatory	US	2/4/2005	Book 50	FDA Submission - IND	L.Weissberger. Protocol Amendment New Investigators, Colque, Noordegraaf, Chazova (AMB-321, AMB-320/321-E) S-067	S-067	64,915
1	Regulatory	US	1/19/2005	Book 50	FDA Submission - IND	L.Weissberger. Protocol Amendment: New Investigators, [illegible] S-066	S-066	64,915
1	Regulatory	US	12/22/2004	Book 50	FDA Submission - IND	L.Weissberger. Protocol Amendment: New Investigators, Taichman, Hurewitz, Gene, Kremer, Abrahamovych (AMB-320, AMB-321, AMB-320/321-E) S-065	S-065	64,915
1	Regulatory	US	12/17/2004	Book 50	FDA Correspondence - Phone call	FDA Contact Report - Telephone. L.Weissberger/W.Link. Subject: Executive CAC decision about lowering dose(s) for 2 year rat and mouse bioassays.	2004-12-17_64915_CORR_PHONE_WEISSBERGER_LINK.pdf	64,915
1	Regulatory	US	12/7/2004	Book 50	FDA Submission - IND	L.Weissberger-Information Amendment-Pharmacology/Toxicology. 2-year Rat and Mouse Carcinogenicity. S-064	S-064	64,915

1	Regulatory	US	**11/12/2004**	Book 50	FDA Submission - IND	**L. Weissberger - Protocol Amendment: New Investigators: Kramer, M.R., Barst, R.J., Lawrence, E.C., Park, M.H., Schilz, R.J. (AMB-321, AMB-320/321-E) S-063**	**S-063**	64,915
1	Regulatory	US	**10/29/2004**	Book 49	FDA Submission - IND	**L. Weissberger - Protocol Amendment: New Investigators: Langleben, D., Carlson,R., Diez,F., Porcile,R., Ubaldini,J.E., Vico, M.L., Tereschenko,S., Semernin,E.N. (AMB-320, AMB-321, AMB-320/321-E) S-062**	**S-062**	64,915
1	Regulatory	US	**10/26/2004**	Book 49	FDA Correspondence - Fax	FDA Correspondence - Fax - Meeting Minutes 10/13/04.	**2004-10-26_64915_CORR_FAX_MTG_MINS_2004-10-13.pdf**	64,915
1	Regulatory	US	**10/22/2004**	Book 49	FDA Submission - IND	**L. Weissberger - Protocol Amendment-New Principal Investigators: Martinez,J.G., Vazquea,J., Chazova,Irina.Y., Kostenko, M.A., Czuriga,I., Landzberg, M.J., (AMB-320, AMB-321, AMB-320/321-E) S-061**	**S-061**	64,915
1	Regulatory	US	**10/5/2004**	Book 49	FDA Submission - IND	**L. Weissberger – Protocol Amendment. New Investigators. M. Amuchastegui,G. Bortman, E. Perna, K. Karlocai, O. Abrahamovysch, G.Dzyak, N. Kopitsa, V. Kovalenko, S. Polyvoda, F. Kleber, P. Podolec, A. Torbicki, V. McLaughlin, A. Towlar (AMB-320, AMB-321, AMB-320/321-E) S-060**	**S-060**	64,915
1	Regulatory	US	**9/27/2004**	Book 49	FDA Submission - IND	**Lynn Weissberger - Type C Meeting Information Package. S-059**	**S-059**	64,915

1	Regulatory	US	**9/7/2004**	Book 48	FDA Submission - IND	**Lynne Weissberger - Protocol Amendment. New Investigators. R. Sulica, I. Czuriga, P. Podolec, A. Torbicki, I. Ben-Dov, R.P. Allen, R.J. Oudiz (AMB-320, AMB-321, AMB-320/321-E) S-058**	**S-058**	64,915
1	Regulatory	US	**8/31/2004**	Book 48	FDA Submission - IND	**Lynne Weissberger - Annual Report 07-03-2003 through 07-02-2004. S-057**	**S-057**	64,915
1	Regulatory	US	**8/27/2004**	Book 48	FDA Submission - IND	**Protocol Amendment - L. Weissberger - Initial Written Report. 15-Day Safety Alert Report. (AMB-320/321-E) S-056**	**S-056**	64,915
1	Regulatory	US	**8/11/2004**	Book 48	FDA Correspondence - Fax	Fax from R. Fortney to L. Weissberger. Subject: Meeting confirmation with FDA for October 13, 2004.	**2004-08-11_64915_CORR_FAX_RFORTNEY_LWEISSBERGER.pdf**	64,915
1	Regulatory	US	**8/10/2004**	Book 48	FDA Submission - IND	**L.Weissberger-Protocol Amendment New Investigators. R.Barst, M.Lamdzberg, M.A.G.Sanchez, J.A.Barbera, D.Badesch, R.Foley (AMB-320, AMB-320/321-E) S-055**	**S-055**	64,915
1	Regulatory	US	**8/9/2004**	Book 48	FDA Submission - IND	**L. Weissberger - Type C Meeting Request to discuss proposed changes to the ambrisentan program. S-054**	**S-054**	64,915
1	Regulatory	US	**7/20/2004**	Book 48	FDA Correspondence - Phone call	FDA Contact Report - Call to Alisea Sermon. Subject: Schedule Type C Meeting.	**2004-07-20_64915_CORR_PHONE_LWEISSBERGER_ASERMON.pdf**	64,915
1	Regulatory	US	**7/21/2004**	Book 48	FDA Correspondence - Email	FDA Contact Report - Email to A. Sermon. Subject: Meeting Request with the Division of Cardio-Renal drug Products.	**2004-07-21_64915_CORR_EMAIL_LWEISSBERGER_ASERMON.pdf**	64,915
1	Regulatory	US	**7/16/2004**	Book 47	FDA Correspondence - Phone call	FDA Contact Report - Call to M. Robb. Subject: Type C Meeting Request.	**2004-07-16_64915_CORR_PHONE_LWEISSBERGER_MROBB.pdf**	64,915

1	Regulatory	US	**7/15/2004**	Book 47	FDA Correspondence - Email	FDA Contact Report - Email to M. Robb. Subject: Ambrisentan, Type C Meeting Request.	**2004-07-15_64915_CORR_EMAIL_LWEISSBERGER_MROBB.pdf**	64,915
1	Regulatory	US	**7/14/2004**	Book 47	FDA Submission - IND	**L. Weissberger- Protocol Amendment- New Investigators- A. Frost, P. Galvez, H. Donoso, M. Delcroix, G. Simonneau, J. Behr, R. Fairman, A. Frost (AMB-320, AMB-321, AMB-320/321-E) S-053**	**S-053**	64,915
1	Regulatory	US	**7/7/2004**	Book 47	FDA Submission - IND	**L. Weissberger- Protocol Amendment- New Investigators- D. Baratz, J. Edelman, N. Hill, I. Robbins, M. Robbins, S. Shapiro, S. Bhorade (AMB-320/321-E) S-052**	**S-052**	64,915
1	Regulatory	US	**6/23/2004**	Book 47	FDA Submission - IND	**L. Weissberger-Protocol Amendment- New Investigators – A. Waxman, P. Corris, A. Peacock, J. Pepke-Zaba, J. Gossage, J. Klinger, K. Mubarak, S. Murali (AMB-320, AMB-321, AMB-320/321-E) S-051**	**S-051**	64,915
1	Regulatory	US	**5/27/2004**	Book 47	FDA Correspondence - Letter	FDA Contact Report -AMB Orphan Drug Application - Amendment - Reference Number: 04-1836	**2004-05-27_ODA_US_AMENDMENT.pdf**	64,915
1	Regulatory	US	**5/7/2004**	Book 47	FDA Submission - IND	**L. Weissberger- Protocol Amendment: New Investigators R. Allen, S. Murali, R. Oudiz, J. Wirth, J. Behr, J. Albert Barbera, C. Black, R. Channick, M. McGoon, F. Torres (AMB-320, AMB-321, AMB-320/321-E) S-050**	**S-050**	64,915
1	Regulatory	US	**5/6/2004**	Book 46	FDA Submission - IND	**L. Weissberger- Protocol Amendment: Change in Protocols: 320, 321, 320/321-E. S-049**	**S-049**	64,915

1	Regulatory	US	**5/3/2004**	Book 46	FDA Correspondence - Phone call	FDA Contact Report - Call to Melissa Robb. Subject: To discuss darusentan submission & PK program for ambrisentan.	**2004-05-03_64915_CORR_PHONE_LWEISSBERGER_MROBB.pdf**	64,915
1	Regulatory	US	**4/28/2004**	Book 46	FDA Correspondence - Phone call	FDA Contact Report - Call to Brad Glasscock, Tan Nguyen. Subject: To clarify request for information from Brad Glasscock.	**2004-04-28_64915_CORR_PHONE_LWEISSBERGER_GLASSCOCK.pdf**	64,915
1	Regulatory	US	**4/22/2004**	Book 46	FDA Correspondence - Email	FDA Contact Report - Email. L.Weissberger/P.Marroum. Email with attached word document - Feedback on Proposed Changes to AMB-320/321-E.	**2004-04-22_64915_CORR_EMAIL_LWEISSBERGER_PMARROUM.pdf**	64,915
1	Regulatory	US	**4/21/2004**	Book 46	FDA Correspondence - Phone call	FDA Contact Report - Dr. Glasscock called to inquire as to the status of the requested amendment.	**2004-04-21_64915_CORR_PHONE_BGLASCOCK_LWEISSBERGER.pdf**	64,915
1	Regulatory	US	**4/12/2004**	Book 46	FDA Submission - IND	**Protocol Amendment - L. Weissberger- New Investigators J. Edelman, J. Mandel, M. Park, R. Schilz, H. Olschewski (AMB-320, AMB-321, AMB-320/321-E) S-048**	**S-048**	64,915
1	Regulatory	US	**4/8/2004**	Book 46	FDA Correspondence - Phone call	FDA Contact Report- Call to Jeffrey Fritsch to inquire the status of application – J. Fritsch was out of office and Mary Grice answered questions.	**2004-04-08_64915_CORR_PHONE_LWEISSBERGER_BGLASSCOCK.pdf**	64,915
1	Regulatory	US	**4/7/2004**	Book 46	FDA Correspondence - Phone call	FDA Contact Report- Comments on proposed changes to extension protocol - pop: K and PK sub study.	**2004-04-07_64915_CORR_PHONE_LWEISSBERGER_MROBB.pdf**	64,915
1	Regulatory	US	**3/26/2004**	Book 45	FDA Submission - IND	**Protocol Amendment - L. Weissberger- New Investigators- N. Hill, C. Jennings, M. McGoon, D. Zwicke, S. Maruti Bhorade (AMB-320, AMB-321, AMB-320/321-E) S-047**	**S-047**	64,915
1	Regulatory	US	**3/25/2004**	Book 45	FDA Submission - IND	**L. Weissberger-Type C Meeting Request. S-046**	**S-046**	64,915
1	Regulatory	US	**3/17/2004**	Book 45	FDA Submission - IND	**L. Weissberger-Pharmacology/Toxicology 2-Year Rat and Mouse Final Protocols. S-045**	**S-045**	64,915

1	Regulatory	US	**3/5/2004**	Book 45	FDA Submission - IND	**Protocol Amendment - L. Weissberger- New Investigators- D. Badesch, R. Foley, E. Lawrence, I. Robbins, S. Shapiro (AMB-320) S-044**	**S-044**	64,915
1	Regulatory	US	**2/27/2004**	Book 44	FDA Submission - IND	**Protocol Amendment - L. Weissberger- New Investigators- R. Channick, K. Mubarak, F. Torres, R. Naeija, N. Galie, A Keogh (AMB-320, AMB-321, AMB-320/321-E) S-043**	**S-043**	64,915
		US	**2/24/2004**	Book 44	FDA Correspondence - Fax	Response to Carcinogenicity Protocol Assessment Request - Final CAC Report.	**2004-02-24_64915_CORR_FAX_SEIFRIED_WALDO.pdf**	64,915
1	Regulatory	US	**2/24/2004**	Book 44	FDA Correspondence - Letter	J. Fritsch- Acknowledge receipt of application for orphan designation submitted.	**2004-02-24_ODA_US_CORR_LETTER_ASSIGN_ODA_NUMBER.pdf**	64,915
1	Regulatory	UK	**2/20/2004**	Book 44	Foreign Correspondence - MHRA	Clinical Trial Application UK - MHRA-Exemption from licenses.	**2004-02-20_64915_MHRA_CORR_LETTER.pdf**	64,915
1	Regulatory	US	**2/16/2004**	Book 44	FDA Submission - IND	**Protocol Amendment - L. Weissberger- New Investigators- J. Gossage, M. Delcroix, G. Simonneau, F. Xaver Kleber, I. Ben-Dov, and P. Engel (AMB-320, AMB-321, AMB-320/321-E) S-042**	**S-042**	64,915
1	Regulatory	US	**2/13/2004**	Book 44	FDA Submission - IND	**L. Weissberger-Information Amendment- Updated IB. S-041**	**S-041**	64,915
1	Regulatory	US	**1/30/2004**	Book 44	FDA Submission - IND	**L. Weissberger-Change in US Agent from Quintiles, Inc. to Myogen, Inc. S-040**	**S-040**	64,915
1	Regulatory	US	**1/28/2004**	Book 44	FDA Correspondence - Fax	Fax - Response to Carcinogenicity Protocol Assessment Request - Final CAC Report.	**2004-01-28_64915_CORR_FAX_FDA.pdf**	64,915
1	Regulatory	US	**1/16/2004**	Book 44	FDA Correspondence - Fax	Z. McDonald- Receipt of request - Serial No. 036 for a special carcinogenicity protocol assessment.	**2004-01-16_64915_CORR_FAX_FDA.pdf**	64,915

1	Regulatory	US	**1/15/2004**	Book 44	FDA Submission - IND	**Protocol Amendment - New Investigators-R. Fairman, M. Robbins, H. Garcia (AMB-320, AMB-320/321-E) S-039**	**S-039**	64,915
1	Regulatory	US	**1/14/2004**	Book 44	FDA Correspondence - Email	Email Communication regarding special assessment for 2-year mouse carcinogenicity protocol.	**2004-01-14_64915_CORR_EMAIL_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**1/12/2004**	Book 44	FDA Submission - IND	**Courtesy copy of Orphan Drug Application (Cover Letter) S-038**	**S-038**	64,915
1	Regulatory	US	**1/6/2004**	Book 44	FDA Submission - IND	**Protocol Amendment - New Investigators- Keogh, Baratz, Engel, Garcia, Klinger (AMB-320-E) S-037**	**S-037**	64,915
1	Regulatory	US	**1/5/2004**	Book 44	FDA Correspondence - Letter	Letter from - M. Gerber to Dr. Haffner about transfer of responsibility as US Agent and Authorized Representative effective Dec. 12, 2003, quintiles, Inc. assumes the responsibility from Myogen, Inc. as the US Agent to interact with the office of Orphan Products Development	**2004-01-05_64915_CORR_LETTER_HAFNER_WALDO.pdf**	64,915
1	Regulatory	US	1/5/2004	Book 44	FDA Correspondence - Letter	Letter from- C. Waldo to Dr. Haffner regarding application for Orphan Drug designation.	2004-01-05A_64915_CORR_LETTER_HAFNER_WALDO.pdf	64,915
1	Regulatory	US	**12/18/2003**	Book 43	FDA Submission - IND	**Request for Special Protocol Assessment 2-Year Mouse Carcinogenicity Protocol. S-036**	**S-036**	64,915
1	Regulatory	US	**12/2/2003**	Book 43	FDA Submission - IND	**Change in Protocol: 220-E. S-035**	**S-035**	64,915
1	Regulatory	US	**11/24/2003**	Book 43	FDA Correspondence - Fax	FDA Contact Report. Fax. Subject: Response to Carcinogenicity Protocol Assessment Request - Final CAC Report - IND 64,915	**2003-11-24_64915_CORR_FAX_SEIFRIED_WALDO.pdf**	64,915
1	Regulatory	US	**10/20/2003**	Book 43	FDA Correspondence - Letter	FDA Contact Report-Z. McDonald-Acknowledgement of receipt from Oct. 13, 2003, request for a special carcinogenicity protocol assessment.	**2003-10-20_64915_CORR_LETTER_ZMCDONALD_MGERBER.pdf**	64,915
1	Regulatory	US	**10/13/2003**	Book 43	FDA Submission - IND	**Request for special protocol assessment 2-Year Rat Carcinogenicity Protocol. S-034**	**S-034**	64,915

1	Regulatory	US	**10/9/2003**	Book 42	FDA Correspondence - Phone call	FDA Contact Report- Response to questions.	**2003-10-09_64915_CORR_PHONE_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**10/8/2003**	Book 42	FDA Correspondence - Email	C. Waldo-Response to Carcinogenicity Protocol Assessment Request.	**2003-10-08_64915_CORR_EMAIL_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**10/8/2003**	Book 42	FDA Submission - IND	**New Phase III Protocols: 320, 321, 320/321-E Response Requested. S-033**	**S-033**	64,915
1	Regulatory	US	**10/7/2003**	Book 42	FDA Correspondence - Email	FDA Contact Report- Email - Phase III Protocols. C. Waldo.	**2003-10-07_64915_CORR_EMAIL_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**10/7/2003**	Book 42	FDA Correspondence - Phone call	FDA Contact Report- Regarding request for feedback.	**2003-10-07_64915_CORR_PHONE_WALDO_ROBB.pdf**	64,915
1	Regulatory	US	**10/7/2003**	Book 42	FDA Correspondence - Phone call	FDA Contact Report- Phone call - Left v-mail regarding request for feedback.	**2003-10-07A_64915_CORR_PHONE_ROBB_WALDO.pdf**	64,915
1	Regulatory	US	**9/9/2003**	Book 42	FDA Correspondence - Fax	FDA Correspondence - Fax - 8/27/03 Meeting Minutes.	**2003-09-09_64915_CORR_FAX_ROBB_WALDO.pdf**	64,915
1	Regulatory	US	**9/9/2003**	Book 42	FDA Correspondence - Phone call	FDA Contact Report- Confirm receipt of fax containing the meeting minutes from the 8/27/2003 meeting with the division.	**2003-09-09_64915_CORR_PHONE_ROBB_WALDO.pdf**	64,915
1	Regulatory	US	**9/9/2003**	Book 42	FDA Submission - IND	**Protocol Amendment: New investigators: D. Badesch, M. McGoon, S. Rich, M . Landzberg, R. Barst (AMB-220-E) S-032**	**S-032**	64,915
1	Regulatory	US	**9/4/2003**	Book 42	FDA Correspondence - Phone call	FDA Contact Report-Special Protocol Assessment.	**2003-09-04_64915_CORR_PHONE_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**9/3/2003**	Book 42	FDA Submission - IND	**IND Annual Report. S-031**	**S-031**	64,915
1	Regulatory	US	**8/27/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report- Verify FDA meeting attendees.	**2003-08-27_64915_CORR_PHONE_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**8/27/2003**	Book 41	FDA Correspondence - Meeting	Meeting Minutes from - August 27, 2003 meeting with FDA.	**2003-08-27_64915_CORR_MEETING_CWALDO_MROBB.pdf**	64,915

1	Regulatory	US	**8/22/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report- End of Phase II Meeting.	**2003-08-22_64915_CORR_PHONE_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**8/8/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report- Copies for August 27 Meeting.	**2003-08-08_64915_CORR_PHONE_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**8/8/2003**	Book 41	FDA Correspondence - Letter	FDA Correspondence - Letter - 4 Additional copies of the info. Package for 8/27/03 meeting.	**2003-08-08_64915_CORR_LETTER_INFO_PKG_COPIES.pdf**	64,915
1	Regulatory	US	**8/7/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report- Confirm FDA receipt of Briefing Document for August 27 Meeting.	**2003-08-07_64915_CORR_PHONE_CWALDO_MROBB.pdf**	64,915
1	Regulatory	US	**8/5/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report-End of Phase II briefing package.	**2003-08-05_64915_CORR_PHONE_MROBB_CWALDO.pdf**	64,915
1	Regulatory	US	**8/5/2003**	Book 41	FDA Submission - IND	**Information Package for August 27, 2003 Meeting. S-030**	**S-030**	64,915
1	Regulatory	US	**7/25/2003**	Book 41	FDA Submission - IND	**Protocol Amendment: New Investigators: Teresa De Marco (AMB-220-E) S-029**	**S-029**	64,915
1	Regulatory	US	**7/10/2003**	Book 41	FDA Submission - IND	**FDA - General Correspondence - Contact Information. S-028**	**S-028**	64,915
1	Regulatory	US	**7/8/2003**	Book 41	FDA Correspondence - Fax	FDA Contact Report -Confirmation of Meeting g: August 27, 2003	**2003-07-08_64915_CORR_FAX_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**7/7/2003**	Book 41	FDA Submission - IND	**Protocol Amendment: New Investigators-I. Robbins, S. Shapiro, AMB-220-E. S-027**	**S-027**	64,915
1	Regulatory	US	**7/2/2003**	Book 41	FDA Submission - IND	**Meeting Request: Type B. Request for Re-Scheduling. S-026**	**S-026**	64,915
1	Regulatory	US	**7/2/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report- M. Robb requested that we resubmit the request to reschedule the end of phase II meeting for IND 64,915	**2003-07-02_64915_CORR_PHONE_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**6/26/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report-R. Fortney checked on request to re-schedule the end-of Phase II meeting with Melissa Robb.	**2003-06-26_64915_CORR_PHONE_RFORTNEY_MENLOW.pdf**	64,915

		US	**6/24/2003**	Book 41	FDA Submission - IND	**IND - Meeting Request - Type B Request for Re-Scheduling. S-025**	**S-025**	64,915
1	Regulatory	US	**6/23/2003**	Book 41	FDA Correspondence - Phone call	FDA Contact Report- M.Robb requested that the end of Phase II meeting originally scheduled for July 11, 2003 be re-scheduled.	**2003-06-23_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**6/13/2003**	Book 41	FDA Submission - IND	**Protocol Amendment: New Investigators and Revision to FDA form 1572 (AMB-220-E) S-024**	**S-024**	64,915
1	Regulatory	US	**5/23/2003**	Book 40	FDA Correspondence - Fax	FDA Contact Report-Fax - Confirmation of 7/11/03.	**2003-05-23_64915_CORR_FAX_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**5/23/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report-M. Robb called Project Manager to confirm receipt of fax	**2003-05-23_64915_CORR_PHONE_ATANNER_MROBB.pdf**	64,915
1	Regulatory	US	**5/15/2003**	Book 40	FDA Correspondence - Fax	FDA Correspondence - Fax - Formal meeting request for an End of Phase II meeting.	**2003-05-15_64915_CORR_FAX_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**5/15/2003**	Book 40	FDA Submission - IND	**Meeting Request : Type B. S-023**	**S-023**	64,915
1	Regulatory	US	**5/6/2003**	Book 40	FDA Submission - IND	**Protocol Amendment- New Investigators. S-022**	**S-022**	64,915
1	Regulatory	US	**5/2/2003**	Book 40	FDA Submission - IND	**IND Safety Report – Follow-up IND Safety Report Mfg. Rpt. No. 29404 (Follow-up 1) S-021**	**S-021**	64,915
1	Regulatory	US	**4/22/2003**	Book 40	FDA Submission - IND	**General Correspondence – Transfer of Regulatory Obligations. S-020**	**S-020**	64,915
1	Regulatory	US	**4/1/2003**	Book 40	FDA Submission - IND	**General Correspondence – Duration of Chronic Toxicity Study. M. Enlow/D. Throckmorton. S-019**	**S-019**	64,915
1	Regulatory	US	**3/20/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Inquire about letter of intent for submission of Special Carcinogenicity Protocol submission.	**2003-03-20_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915

1	Regulatory	US	**3/19/2003**	Book 40	FDA Submission - IND	**General Correspondence – Copy of letter to investigators regarding two deaths (unrelated) and consent form changes. M.Enlow/D.Throckmorton. S-018**	**S-018**	64,915
1	Regulatory	US	**3/11/2003**	Book 40	FDA Submission - IND	**General Correspondence – Copy of Investigator Notification of IND Safety Report for elevated Liver Function Tests. M.Enlow/D.Throckmorton. S-017**	**S-017**	64,915
1	Regulatory	US	**3/10/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Express concern that report of elevated LFTs to greater than 8 times upper limit of normal was not initially considered a SAE and suggest the sponsors remind investigators of potential for hepatotoxicity and need for SAE reporting of such event. JPelayo, MD/M.Enlow.	**2003-03-10_64915_CORR_PHONE_JPELAYO_MENLOW.pdf**	64,915
1	Regulatory	US	**3/7/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Project Manager communicates FDA decision on extension protocol AMB-220-E. L.Tanner/M.Robb.	**2003-03-07_64915_CORR_PHONE_MROBB_ATANNER.pdf**	64,915
1	Regulatory	US	**3/5/2003**	Book 40	FDA Submission - IND	**IND 15-Day ADR Report. M. Enlow/FDA. S-016**	**S-016**	64,915
1	Regulatory	US	**3/5/2003**	Book 40	FDA Correspondence - Fax	FDA Correspondence - Fax - Fax of submission dated 3/5/03 S-016.	**2003-03-05_64915_CORR_FAX_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**2/28/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Discuss case of increased liver function tests reported in study AMB-220.	**2003-02-28_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**2/27/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Check status of Division's review of extension Protocol, AMB-220-E. M. Enlow/M. Robb	**2003-02-27_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**2/11/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Discuss Typo's of year submitted on Protocol AMB220-E.	**2003-02-11_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**2/7/2003**	Book 40	FDA Submission - IND	**Protocol Amendment: New Protocol AMB 220-E. S-015**	**S-015**	64,915

1	Regulatory	US	**2/5/2003**	Book 40	FDA Submission - IND	**Protocol Amendment: New Investigators –McGoon, Landzberg, Marco. S-014**	**S-014**	64,915
1	Regulatory	US	**1/27/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Inform sponsors the Division is still discussing internally the open-label extension study, protocol AMB-222, and timing relative to the non-rodent chronic toxicity study.	**2003-01-27_64915_CORR_PHONE_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**1/24/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Discuss open-label extension study, protocol AMB-222, and timing relative to non-rodent chronic toxicity study. M. Robb & M. Enlow	**2003-01-24_64915_CORR_PHONE_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**1/20/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report: Message left-update on feedback request for proposal to provide open-label treatment beyond 24 wks.	**2003-01-20_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**1/14/2003**	Book 40	FDA Submission - IND	**Response to FDA Request – submitting safety monitoring plans for 12-wk Open-label Extension Period for AMB 220 and draft safety monitoring plans for AMB 222. S-013**	**S-013**	64,915
1	Regulatory	US	**1/14/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report – Confirm 12-wk extension period in Protocol AMB-220 could proceed.	**2003-01-14_64915_CORR_PHONE_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**1/13/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report – FDA Project Manager called to request additional IND 64,915 information. M.Robb and A. Tanner	**2003-01-13_64915_CORR_PHONE_MROBB_ATANNER.pdf**	64,915
1	Regulatory	US	**1/13/2003**	Book 40	FDA Correspondence - Fax	FDA Contact Report – Fax - Response to FDA Request for additional information regarding IND 64,915.	**2003-01-13_64915_CORR_FAX_TANNER_MROBB.pdf**	64,915
1	Regulatory	US	**1/10/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report – Discuss causes of death in some animals in 26-wk rat toxicity study. M. Enlow & W. Link.	**_64915_CORR_PHONE_MENLOW_M**	64,915
1	Regulatory	US	**1/10/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report – Inquire whether Melissa could provide update on Division's position on the explanation given for mortality in 26 wk rat toxicity study and moving into the extension phase of the clinical study.	**2003-01-10A_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915

1	Regulatory	US	**1/9/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report – Clarify their internal mtg. to discuss 26-wk toxicity studies & open-label extensions to the clinical study.	**2003-01-09_64915_CORR_PHONE_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**1/9/2003**	Book 40	FDA Submission - IND	**Protocol Amendment – New Investigators: AMB-220 Simonneau, France; McLaughlin, Robbins, & Shapiro, United States. S-012**	**S-012**	64,915
1	Regulatory	US	**1/9/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report – Arrange time for phone conference to discuss questions about he 26-wk toxicity study. W. Link , M. Enlow.	**2003-01-09_64915_CORR_PHONE_MENLOW_WLINK.pdf**	64,915
1	Regulatory	US	**1/8/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report - To clarify the date of their internal meeting to discuss the 26-week toxicity studies and the open-label extensions to the clinical study.	**2003-01-08_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**1/2/2003**	Book 40	FDA Submission - IND	**General Correspondence – Rationale & Study Summary for additional long-term protocol. From Quintiles to Dr. Throckmorton. S-011**	**S-011**	64,915
1	Regulatory	US	**1/2/2003**	Book 40	FDA Correspondence - Phone call	FDA Contact Report – Informed Melissa Robb that faxed copy of submission w- Rationale & Study Summary for Protocol AMB-222 sent.	**2003-01-02_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	1/2/2003	Book 40	FDA Correspondence - Fax	FDA Contact Report – Fax - Copy of submission with rationale and study summary of S-011.	2003-01-02_64915_CORR_FAX_MENLOW_MROBB.pdf	64,915
1	Regulatory	US	**12/30/2002**	Book 2	FDA Correspondence - Phone call	FDA Contact Report – Follow-up regarding extension of treatment beyond 6 months.	**2002-12-30_64915_CORR_PHONE_ENLOW_ROBB.pdf**	64,915
1	Regulatory	US	**12/24/2002**	Book 2	FDA Correspondence - Phone call	FDA Contact Report – Follow-up regarding extension of treatment beyond 6 months.	**2002-12-24_64915_CORR_PHONE_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**12/23/2002**	Book 2	FDA Correspondence - Phone call	FDA Contact Report – Inquire about date of Division's Internal mtg. To discuss 26 wk toxicity studies and whether Division would consider clinical extension protocol for treatment beyond 6 months.	**2002-12-23_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915

1	Regulatory	US	**12/12/2002**	Book 2	FDA Correspondence - Phone call	FDA Contact Report – Informed Quintiles that the Division scheduled an internal mtg. In January 2003 to discuss 26 wk toxicology studies.	**2002-12-12_64915_CORR_PHONE_MROBB_MENLOW.pdf**	64,915
1	Regulatory	US	**12/11/2002**	Book 2	FDA Correspondence - Phone call	FDA Contact Report – Informed Melissa Robb, new FDA project mgr. That the 26 wk toxicity study submitted and receipt confirmed.	**2002-12-11_64915_CORR_PHONE_MENLOW_MROBB.pdf**	64,915
1	Regulatory	US	**12/10/2002**	Book 2	FDA Correspondence - Phone call	FDA Contact Report – Informed Zelda that 26 wk toxicology draft study report submitted. Zelda to provide name & phone # of new FDA project mgr for IND.	**2002-12-10_64915_CORR_PHONE_MENLOW_ZMCDONALD.pdf**	64,915
1	Regulatory	US	**12/9/2002**	Book 34-39	FDA Submission - IND	**Vol. 1 - 6 - Response to FDA Request for Information – 26 wk. Toxicity Studies (Draft Reports: Dog and Rat) S-010**	**S-010**	64,915
1	Regulatory	US	**11/8/2002**	Book 2	FDA Submission - IND	**Protocol Amendment - New Investigators – Olschewski, Schilz, Germany and United States (AMB-220) S-009**	**S-009**	64,915
1	Regulatory	US	**11/6/2002**	Book 2	FDA Submission - IND	**Information Amendment: Clinical. S-008**	**S-008**	64,915
1	Regulatory	US	**10/29/2002**	Book 1	FDA Submission - IND	**Response to FDA Request for Information – Chemistry, Manufacturing & Controls. S-007**	**S-007**	64,915
1	Regulatory	US	**10/18/2002**	Book 1	FDA Submission - IND	**New Investigators – Keogh, Naeije, Hoeper, Galie, Rubin, Frost, Zwicke, Australia, Belgium, Germany, Italy and United States (AMB-220) S-006**	**S-006**	64,915
1	Regulatory	US	**9/25/2002**	Book 1	FDA Submission - IND	**Protocol Amendment – New Investigators – DBadesch and Rdoyle (AMB-220) S-005**	**S-005**	64,915
1	Regulatory	US	**9/20/2002**	Book 1	FDA Correspondence - Letter	FDA Contact Report – FDA completed chemistry review of 7-17-2002 (S-002) submission & provided comments-requests. Dthrockmorton-JMFreytag-Myogen Menlow.	**2002-09-20_64915_CORR_LETTER_DTHROCKMORTON_WFREYTAG.pdf**	64,915
1	Regulatory	US	**9/10/2002**	Book 1	FDA Submission - IND	**Protocol Amendment – New Investigators US: ROudiz 004 (AMB-220) - S-004**	**S-004**	64,915

1	Regulatory	US	**8/30/2002**	Book 1	FDA Submission - IND	**Protocol Amendment – Submitted Amendment 1, dated 7-26-2002 for Protocol No. AMB-220 (No Suggestions) - S-003**	**S-003**	64,915
1	Regulatory	US	**7/31/2002**	Book 1	FDA Correspondence - Letter	FDA Contact Report – Letter from FDA with regard to Clinical Trials Data Bank, asking for review of protocol submitted with S-000 to determine if it is a trial for a serious disease or condition and if it is a trial to test effectiveness.	**2002-07-31_64915_CORR_LETTER_JWOODCOCK_CKIRK.pdf**	64,915
1	Regulatory	US	**7/17/2002**	Book 33	FDA Submission - IND	**Information Amendment: Amendment to provide updated info for drug substance and drug product. (CHEMISTRY) - S-002**	**S-002**	64,915
1	Regulatory	US	**6/28/2002**	Book 1	FDA Submission - IND	**Information Amendment: Clinical Revised Informed Consent Form - S-001**	**S-001**	64,915
1	Regulatory	US	**6/28/2002**	Book 1	FDA Correspondence - Fax	FDA Contact Report – Inform Zelda a revised Informed Consent form for Protocol AMB-220 was being sent to her as requested by Dr. Stockbridge.	**2002-06-28_64915_CORR_FAX_MENLOW_ZMCDONALD.pdf**	
1	Regulatory	US	**6/28/2002**	Book 1	FDA Correspondence - Phone call	FDA Contact Report – Inform Zelda a revised Informed Consent form for Protocol AMB-220 was being sent to her as requested by Dr. Stockbridge.	**2002-06-28_64915_CORR_PHONE_MENLOW_ZMCDONALD.pdf**	64,915
1	Regulatory	US	**6/25/2002**	Book 1	FDA Correspondence - Phone call	FDA Contact Report – Request Chg to Informed Consent document & discuss Pharm-Tox required for supporting open-label extension study.	**2002-06-25_64915_CORR_PHONE_NSTOCKBRIDGE_MENLOW.pdf**	64,915
1	Regulatory	US	**6/25/2002**	Book 1	FDA Correspondence - Phone call	FDA Contact Report – Called Monica Cooper to discuss questions about stability data for the drug product.	**2002-06-25_64915_CORR_PHONE_MENLOW_MCOOPER.pdf**	64,915
1	Regulatory	US	**6/24/2002**	Book 1	FDA Correspondence - Phone call	FDA Contact Report – Monica Cooper call Marguerite -asked a few questions about the stability data for the drug product.	**2002-06-24_64915_CORR_PHONE_MCOOPER_MENLOW.pdf**	64,915
1	Regulatory	US	**6/10/2002**	Book 1	FDA Correspondence - Letter	FDA Correspondence - Letter - Acknowledgement of receipt of IND Application submitted.	**2002-06-10_64915_CORR_LETTER_ZMCDONALD_WFREYTAG.pdf**	

1	Regulatory	US	**6/6/2002**	Book 1	FDA Correspondence - Phone call	FDA Contact Report – To check-confirm receipt by Zelda of IND Submission.	**2002-06-06_64915_CORR_PHONE_ZMCDONALD_MENLOW.pdf**	64,915
1	Regulatory	US	**6/3/2002**	Book 1	FDA Correspondence - Phone call	FDA Contact Report – Inform Zelda BSF 208075 IND for PAH was shipped to FDA on June 3, 2002.	**2002-06-03_64915_CORR_PHONE_MENLOW_ZMCDONALD.pdf**	64,915
1	Regulatory	US	6/3/2002	Book 3 32	FDA Submission - IND	Vol. 1 - 30 - Initial Submission - BSF 208075 - IND - Pulmonary Arterial Hypertension Protocol AMB-220 S-100	S-000	64,915

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LINK TO NDA AMENDMENTS

Product	Department	Country	Document Date	Book Number	Document Type	Document Title	E-Copy	Keywords
1	Regulatory	US	**7/20/2007**	Temp 6	FDA Correspondence - Phone	H.Isokoski/D.Brum - phone call. Subject: Spanish translations of the RiskMAP tools. New reminder tools for LEAP. Correct address for waiver request for MedWatch forms for non-serious and labeled adverse events (Aes)	**2007-07-20_22081_CORR_PHONE_HISOKOSKI_DBRUM.pdf**	22-081
1	Regulatory	US	**7/20/2007**	Temp 6	FDA Correspondence - Email	D.Brum - 7/20/2007 on foreign language translation.	**2007-07-20_22081_CORR_EMAIL_HISOKOSKI_DBRUM.pdf**	22-081
1	Regulatory	US	**7/16/2007**	Temp 6	FDA Correspondence - Email	D.Brum/H.Isokoski - Postmarketing Study Commitment Correspondence and Patent Information. NDA 22-081	**2007-07-16_22081_CORR_EMAIL_HISOKOSKI_DBRUM.pdf**	22-081
1	Regulatory	US	**7/13/2007**	Temp 6	FDA Correspondence - Email	D.Brum/H.Isokoski - Postmarketing Study Commitment Correspondence and Patent Information. NDA 22-081	**2007-07-13_22081_CORR_EMAIL_HISOKOSKI_DBRUM.pdf**	22-081
1	Regulatory	US	**7/11/2007**	Temp 6	FDA Correspondence - Phone	D.Brum/H.Isokoski - Letairis RiskMAP. To update the Division on the status of the submission and seek their advice on correct process.	**2007-07-11_22081_CORR_PHONE_HISOKOSKI_DBRUM.pdf**	22-081
1	Regulatory	US	**7/11/2007**	Temp 6	FDA Correspondence - Email	D.Brum/H.Isokoski - Letairis RiskMAP.	**2007-07-11_22081_CORR_EMAIL_HISOKOSKI_DBRUM.pdf**	22-081
1	Regulatory	US	**7/9/2007**	Temp 6	FDA Correspondence - Phone	T.Marshall/T.Bouie - Phone calls on June21, June 29 and July 9, 2007. Subject: Post-Approval Supplement for Change to RPM in Dissolution Method. NDA 22-081	**2007-07-09_22081_CORR_PHONE_TBOUIE_TMARSHALL.pdf**	22-081

1	Regulatory	US	**7/9/2007**	Temp 6	FDA Correspondence - Email	T.Marshall/T.Bouie - Teleconference (July 10) information with the list of attendees from Gilead and FDA attendees. NDA 22-081 for Letairis Tablets-Proposal for CBE-30 Post Approval Supplement-Increase in Dissolution Method Paddle Speed.	**2007-07-09_22081_CORR_EMAIL_TMARSHALL_TBOUIE.pdf**	22-081
1	Regulatory	US	**7/6/2007**	Temp 6	FDA Correspondence - Email	L.Tanner/D.Brum - Notification of Last Day at Gilead.	**2007-07-06_22081_CORR_EMAIL_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**7/3/2007**	Temp 6	FDA Correspondence - Email	L.Tanner/D.Brum - Respond from D.Brum to the questions regarding the Revising RiskMAP and Materials to Reflect "Prescriber"	**2007-07-03_22081_CORR_EMAIL_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**7/2/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum - Subject: Pediatric Plan. Revisions to RiskMAP and educational materials.	**2007-07-02_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**7/2/2007**	Temp 6	FDA Correspondence - Email	L.Tanner/D.Brum - Proposed Plan for Revising RiskMAP and Materials to Reflect "Prescriber"	**2007-07-02_22081_CORR_EMAIL_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/22/2007**	Temp 6	FDA Correspondence - Email	T.Marshall/T.Bouie - Proposal for CBE-30 Post Approval Supplement_ Increase in Dissolution Method Paddle Speed. NDA 22-081	**2007-06-22_22081_CORR_EMAIL_TBOUIE_TMARSHALL.pdf**	22-081
1	Regulatory	US	**6/21/2007**	Temp 6	FDA Correspondence - Phone	T.Marshall/S.Goldie - Post-Approval Supplement for Change to RPM in Dissolution Method. NDA 22-081	**2007-06-21_22081_CORR_PHONE_TMARSHALL_SGOLDIE.pdf**	22-081
1	Regulatory	US	**6/19/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum - Subject: Administrative process for post-approval submissions of PI to the NDA	**2007-06-19_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/15/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum - Subject: Final processes for approval. NDA 22-081	**2007-06-15_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/15/2007**	Temp 6	FDA Correspondence - Letter	R.Temple/L.Tanner - The NDA 22-081 - Letairis, Approval Letter from FDA. PI attached.	**\2007-06-15_22081_CORR_LETTER_RTEMPLE_LTANNER.pdf**	22-081
1	Regulatory	US	**6/15/2007**	Temp 6	Internal Correspondence - Labeling Approval	ABS - GS22-081-000: LETAIRIS (ambrisentan) 5 and 10 mg tablets - RAAN CMC - Approved in the US on June 15, 2007	**2007-06-15_22081_CORR_RAAN_NOTIFICATION.pdf**	22-081

1	Regulatory	US	**6/14/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum, T.Marciniak, J.Hung - Resolve remaining issues with PI.	**2007-06-14_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/13/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum - Issues with opening files during Label Negotiation. Cancellation of teleconference between Gilead and FDA.	**2007-06-13_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/12/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum, J.Weaver, S.Berkman - Remaining issues with the RiskMAP	**2007-06-12_22081_CORR_PHONE_LTANNER_DBRUM_2.pdf**	22-081
1	Regulatory	US	**6/12/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum - Final inspection report for Site #207 (Nazzareno Galie) Italy. Next steps for submitting Gilead comments for PI. Teleconference with FDA on Wednesday, 13 June 2007. Teleconference to discuss cyclosporine contraindication.	**2007-06-12_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/11/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/T.Marciniak - Feedback regarding FDA comments to PI.	**2007-06-11_22081_CORR_PHONE_LTANNER_TMARCINIAK.pdf**	22-081
1	Regulatory	US	**6/11/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/R.Fortney - The phone calls (6/8/2007 & 6-11-2007) to proactively schedule teleconference to resolve any remaining NDA issues, particularly with the PI.	**2007-06-11_22081_CORR_PHONE_LTANNER_RFORTNEY.pdf**	22-081
1	Regulatory	US	**6/11/2007**	Temp 6	FDA Correspondence - Email	T.Marshall/G.Scott - Attachment NDA 22-081 Amend 019. Summary of CMC Agreements Reached During June 8, 2007 CMC Teleconference	**2007-06-11_22081_CORR_EMAIL_SGOLDIE_TMARSHALL.pdf**	22-081
1	Regulatory	US	**6/11/2007**	Temp 6	FDA Correspondence - Email	T.Marshall/G.Scott - Update on Gilead's ABS NDA 22-081 Amend 019. Summary of CMC Agreements Reached During June 8, 2007 CMC Teleconference	**2007-06-11_22081_CORR_EMAIL_SGOLDIE_TMARSHALL_1.pdf**	22-081
1	Regulatory	US	**6/8/2007**	Temp 6	FDA Correspondence - Phone	L.Tanner/T.Marciniak - Feedback regarding FDA comments to PI.	**2007-06-08_22081_CORR_PHONE_LTANNER_TMARCINIAK.pdf**	22-081
1	Regulatory	US	**6/8/2007**	Temp 6	FDA Correspondence - Email	T.Marshall/G.Scott - T Con participants.	**2007-06-08_22081_CORR_EMAIL_SGOLDIE_TMARSHALL_1.pdf**	22-081

1	Regulatory	US	6/7/2007	Temp 6	FDA Correspondence - Email	D.Brum/L.Tanner - Notifications about comments on PI.	2007-06-07_22081_CORR_EMAIL_LTANNER_DBRUM_2.pdf	22-081
1	Regulatory	US	6/7/2007	Temp 6	FDA Correspondence - Phone	L.Tanner/D.Brum. The phone calls on 06/06/07 and 06/07/07. Process and Timing for Receiving FDA Comments to PI. Process for submitting revised RiskMAP and associated Materials.	2007-06-07_22081_CORR_PHONE_LTANNER_DBRUM.pdf	22-081
1	Regulatory	US	6/7/2007	Temp 6	FDA Correspondence - Email	L.Tanner/D.Brum. NDA 22-081: Tracleer Label	2007-06-07_22081_CORR_EMAIL_LTANNER_DBRUM_1.pdf	22-081
1	Regulatory	US	6/7/2007	Temp 6	FDA Correspondence - Email	L.Tanner/D.Brum. NDA 22-081: Comments on Proposed RiskMAP	2007-06-07_22081_CORR_EMAIL_LTANNER_DBRUM.pdf	22-081
1	Regulatory	US	6/7/2007	Temp 6	FDA Correspondence - Phone	L.Tanner/M.Gordon - Subject: Processes and Timing for Receiving FDA Comments to PI. Processes for submitting revised RiskMAP and associated Materials.	2007-06-07_22081_CORR_PHONE_LTANNER_DBRUM_2.pdf	22-081
1	Regulatory	US	6/7/2007	Temp 6	FDA Correspondence - Phone	L.Tanner/M.Gordon - The phone calls to confirm that CRF pages for subject 2050/248-001resent and that there are no further outstanding issues regarding input into the PI.	2007-06-07_22081_CORR_EMAIL_LTANNER_MGORDON.pdf	22-081
1	Regulatory	US	6/6/2007	Book 5	FDA Correspondence - Email	M.Gordon/L.Tanner - &-day report; Subject 2050/248-001 (updated forms). The CRF's forms attached.	2007-06-06_22081_CORR_EMAIL_LTANNER_MGORDON_1.pdf	22-081
1	Regulatory	US	6/6/2007	Book 5	FDA Correspondence - Email	M.Gordon/L.Tanner - Message email from May 29, 2007 has been lacked.	2007-06-06_22081_CORR_EMAIL_LTANNER_MGORDON.pdf	22-081
1	Regulatory	US	6/6/2007	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. NDA 22-081: Reformatted MedGuide for LETAIRIS™(ambrisentan)	2007-06-06_22081_CORR_EMAIL_LTANNER_DBRUM.pdf	22-081
1	Regulatory	US	6/5/2007	Book 5	FDA Correspondence - Email	T.Marshall/G.Scott - The FDA participants - May 23, 2007 teleconference regarding NDA 22-081	2007-06-05_22081_CORR_EMAIL_SGOLDIE_TMARSHALL.pdf	22-081
1	Regulatory	US	6/5/2007	Book 5	FDA Correspondence - Phone	L.Tanner/D.Brum. Two phone calls on 06/04/07 and 06/05/0. Process for finalizing Medication Guide, PI, and RiskMAP	2007-06-05_22081_CORR_PHONE_LTANNER_DBRUM.pdf	22-081

1	Regulatory	US	**6/4/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. RiskMAP revised proposal.	**2007-06-04_22081_CORR_EMAIL_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/2/2007**	Book 5	FDA Correspondence - Email	D.Brum/L.Tanner - MedGuide and PI	**2007-06-02_22081_CORR_EMAIL_DBRUM_LTANNER.pdf**	22-081
1	Regulatory	US	**6/1/2007**	Book 5	FDA Correspondence - Email	T.Marshall/S.Goldie. The response to CMC specification changes discussed during May 23, 2007 CMC teleconference. NDA 22-081 Amendment 0017 attached.	**2007-06-01_22081_CORR_EMAIL_SGOLDIE_TMARSHALL.pdf**	22-081
1	Regulatory	US	**6/1/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. E-mail from Dan Brum, FDA Project Manager, who has requested that Gilead resend the Medication Guide for ambrisentan that "looks" like Tracleer. Attached are the Medication Guides for Tracleer and Letairis.	**2007-06-01_22081_CORR_EMAIL_DBRUM_LTANNER_1.pdf**	22-081
1	Regulatory	US	**6/1/2007**	Book 5	FDA Correspondence - Phone	L.Tanner/D.Brum. Subject: Process for resolving PI Issues. FDA Minutes from 25 May 2007 Teleconference. Company Audit Details Dr.Galie.	**2007-06-01_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**6/1/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. Email with two attachments. Subject: The Gilead details of the audit at Dr. Galie's site.	**2007-06-01_22081_CORR_EMAIL_DBRUM_LTANNER.pdf**	22-081
1	Regulatory	US	**6/1/2007**	Book 5	FDA Correspondence - Email - Meeting Minutes from May 25, 2007	D.Brum/L.Tanner. Email with the FDA Meeting Minutes from May 25, 2007.	**2007-06-01_22081_CORR_EMAIL_DBRUM_LTANNER_2.pdf**	22-081
1	Regulatory	US	**5/31/2007**	Book 5	FDA Correspondence - Phone	L.Tanner/D.Brum - Phone contacts, May 18 - May 31, 2007. Subjects: Response to preliminary RiskMAP comments and finalization of RiskMAP. FDA comments to PI.	**2007-05-31_22081_CORR_PHONE_LTANNER_DBRUM.pdf**	22-081
1	Regulatory	US	**5/31/2007**	Book 5	FDA (DDMAC) Correspondence - Fax	J.Acbay/L.M.Hubbard. Fax regarding NDA 22-081 Letairis MACMIS ID # 15246. Comments from the DDMAC on the first submission.	**2007-05-31_22081_CORR_DDMAC_FAX.pdf**	22-081
1	Regulatory	US	**5/30/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brunn. Response to FDA Comments to RiskMAP. Cover Letter (Amendment No. 16 to NDA 22-081) attached.	**2007-05-30_22081_CORR_EMAIL_LTANNER_DBRUM.pdf**	22-081

1	Regulatory	US	**5/25/2007**	Book 5	FDA Correspondence - Email	L.Tanner/M.Gordon. 7 day report; CRF 248-001-2020	**2007-05-25_22081_CORR_EMAIL_LTANNER_MGORDON.pdf**	22-081
1	Regulatory	US	**5/24/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. Confirm Teleconference Time (2:30 EDT) and addition of Jennifer Stewart as a Participant.	**2007-05-24_22081_CORR_EMAIL_DBRUM_LTANNER_3.pdf**	22-081
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1	Regulatory	US	**5/24/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. FDA comments to Packaging	**2007-05-24_22081_CORR_EMAIL_DBRUM_LTANNER.pdf**	22-081
1	Regulatory	US	**5/23/2007**	Book 5	FDA Correspondence - Email	T.Marshall/S.Goldie. Ambrisentan Registration Tablets Dissolutions Data.	**2007-05-23_22081_CORR_EMAIL_SGOLDIE_TMARSHALL.pdf**	22-081
1	Regulatory	US	**5/22/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. Confirmation of Participants and Call-in Number for FDA-Gilead Teleconference 05/25/2007.	**2007-05-22_22081_CORR_EMAIL_DBRUM_LTANNER_1.pdf**	22-081
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1	Regulatory	US	**5/21/2007**	Book 5	FDA Correspondence - Email	L.Tanner/D.Brum. Acceptability of Revised Labeling (Primary and Secondary Packaging). NDA 22-081.	**2007-05-21_22081_CORR_EMAIL_DBRUM_LTANNER.pdf**	22-081
1	Regulatory	US	**5/17/2007**	Book 5	FDA Correspondence - Letter	E.Fromm/L.Tanner. Discipline Review Letter. The comments on the RiskMAP portion of NDA 22-081 from the Office of Surveillance and Epidemiology.	**2007-05-17_22081_CORR_LETTER_EFROMM_LTANNER.pdf**	22-081
1	Regulatory	US	**5/14/2007**	Book 5	FDA Correspondence - Phone	T.Marshall/S.Goldie (Calles made on 4/30/07, 05/02/07, 05/03/07, 05/08/07, 05/14/07) - CMC Information Request, NDA Amendment 13: Updating List of Establishments and Pre-Approval Inspections. NDA 22-081.	**2007-05-14_22081_CORR_PHONE_SGOLDIE_TMARSHALL.pdf**	22-081

1	Regulatory	US	**5/11/2007**	Book 5	FDA Correspondence - Letter	L.Tanner/D.Brum. Desk Copies. 022081 - Amendment No. 14. Briefing Document for 25 May 2007	**2007-05-14_22081_CORR_EMAIL_DBRUM_LTANNER.pdf**	22-081
1	Regulatory	US	**5/9/2007**	Book 5	FDA Correspondence - Email	T.Marshall/S.Goldie - Response to the 8 comments/questions letter from 04/30/2007 . NDA 22-081	**2007-05-09_22081_CORR_EMAIL_SGOLDIE_TMARSHALL.pdf**	22-081
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1	Regulatory	US	**4/30/2007**	Book 4	FDA Correspondence - Letter	R.Sood/T.Marshall. Information request letter from FDA (review and comments of CMC section for NDA 22-081).	**2007-04-30_22081_CORR_LETTER_RSOOD_TMARSHALL.pdf**	22-081
1	Regulatory	US	**4/30/2007**	Book 4	FDA Correspondence - Phone	L.Tanner/M.Robb. Two phone calls on 4/27/07 and 4/30/07. Subject: Briefing document for May 25 teleconference to discuss proposal to measure 6MWD at trough and peak. NDA 22-081.	**2007-04-30_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
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1	Regulatory	US	**4/26/2007**	Book 4	FDA Correspondence - Phone	L.Tanner/M.Robb - Three phone calls on 4/20/07, 4/24/07, 4/26/07. Subject: Plan Promotional Materials; DMETS Comments; Process Labeling Revisions NDA 22-081	**2007-04-26_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
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1	Regulatory	US	**4/17/2007**	Book 4	FDA Correspondence - Phone	T.Marshall/S.Goldie - Three phone calls on 04/09/07, 04/16/07 and 04/17/07 Subject: Proposed "CMC" Amendment to Ambrisentan NDA to revise listed establishments/functions and to provide corrections to typos/minor errors. NDA 22-081	**2007-04-17_22081_CORR_PHONE_TMARSHALL_SGOLDIE.pdf**	22-081
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1	Regulatory	US	**4/16/2007**	Book 4	FDA Correspondence - Fax	M.Robb/L.Tanner - The FDA Teleconference Meeting Minutes (March 29, 2007). NDA 22-081.	**2007-04-16_22081_CORR_FAX_LTANNER_MROBB_MEETING_MINUTES.pdf**	22-081
1	Regulatory	US	**4/16/2007**	Book 4	FDA Correspondence - Email	L.Tanner/P.Hinderling - Follow-up email to request validation dilution.	**2007-04-16_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**4/16/2007**	Book 4	FDA Correspondence - Phone	L.Tanner/M.Robb - Confirm the date and time for teleconference (Amendment to AMB-323). Confirm name of new Project Manager. NDA 22-081	**2007-04-16_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**4/16/2007**	Book 4	FDA Correspondence - Email	L.Tanner/P.Hinderling - Response to Questions Regarding Dissolution Profiles; NDA 22-081	**2007-04-16_22081_CORR_EMAIL_LTANNER_PHINDERLING_1.pdf**	22-081
1	Regulatory	US	**4/13/2007**	Book 4	FDA Correspondence - Email	L.Tanner/M.Robb - Request for Teleconference: Advice Clinical Inspection.	**2007-04-13_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**4/13/2007**	Book 4	FDA Correspondence - Phone	L.Tanner/M.Robb - Phone calls on 04/12/07 and 04/13/07 - Clinical Inspection for Site #207 (Nazzareno	**2007-04-13_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**4/12/2007**	Book 4	FDA Correspondence - Email	L.Tanner/M.Robb - Email to M. Robb indicating that Gilead acknowledged and understood the Clinical Pharmacology issues that P. Hinderling addressed in his written comments (03/29/07 - FDA teleconference). NDA 22-081	**2007-04-12_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**4/12/2007**	Book 4	FDA Correspondence - Email	L.Tanner/P.Hinderling - Response to Questions Regarding Dissolution Profiles; NDA 22-081	**2007-04-12_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**4/9/2007**	Book 4	FDA Correspondence - Phone	L.Tanner/M.Robb. Subject: Status of scheduling teleconference regarding plan to support once-daily dosing. Submission of promotional materials.	**2007-04-09_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**4/5/2007**	Book 4	FDA Correspondence - Email	L.Tanner/P.Hinderling - Request from P. Hinderling requesting F2 tests of respective dissolution profiles are various pHs for clinical and commercial products.	**2007-04-05_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081

1	Regulatory	US	**4/4/2007**	Book 4	FDA Correspondence - Phone	L.Curran/V.Ventura - Clarification of submission format. NDA 22-081	**2007-04-04_22081_CORR_PHONE_LCURRAN_VVENTURA.pdf**	22-081
1	Regulatory	US	**4/3/2007**	Book 4	FDA Correspondence - Email	L.Tanner/M.Robb - Request for Meeting to discuss Dosing Interval; Follow-up to March 29 Meeting. NDA 22-081	**2007-04-03_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/28/2007**	Book 3	FDA Correspondence - Phone	L.Tanner/M.Robb. Three phone calls on 03/26/07, 03/27/07and 03/28/07. Subjects: Preparation for March 29, 2007 90-Day Teleconference (NDA review status). Amendment No.8. Issues with e-mails sent to Melissa Robb. NDA 22-081.	**2007-03-28_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/28/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Summary of Amendments submitted or will be submitted to NDA 22-081.	**2007-03-28_22081_CORR_EMAIL_LTANNER_MROBB_1.pdf**	22-081
1	Regulatory	US	**3/28/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Plan for submitting electronic datasets are acceptable.	**2007-03-28_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/27/2007**	Book 3	FDA Correspondence - Fax	L.Tanner/M.Robb - Pre-Meeting Comments NDA 22-081	**2007-03-27_22081_CORR_FAX_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/27/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Revised List of Gilead Participants and Call-in Number. NDA 22-081	**2007-03-27_22081_CORR_EMAIL_LTANNER_MROBB_2.pdf**	22-081
1	Regulatory	US	**3/27/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - List of Gilead Participants and Call-in Number. NDA 22-081	**2007-03-27_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/26/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Response to questions in e-mail dated 9/03/07; Amendment No. 8; NDA 22-081	**2007-03-26_22081_CORR_EMAIL_LTANNER_MROBB_1.pdf**	22-081
1	Regulatory	US	**3/26/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Word questions submitted in meeting request (Amendment No.5). NDA 22-081	**2007-03-26_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/22/2007**	Book 3	FDA Correspondence - Phone	M.Plamondon/E.Smith - Mr. Smith was following up on Gilead Colorado's registration as a manufacturer.	**2007-03-22_22081_CORR_PHONE_MPLAMONDON_ESMITH.pdf**	22-081

1	Regulatory	US	**3/20/2007**	Book 3	FDA Correspondence - Phone	L.Tanner/S.Gershon - FDA Inspection for Site # 207 (Nazzareno Galie) Italy. NDA 22-081	**2007-03-20_22081_CORR_PHONE_LTANNER_SGERSHON.pdf**	22-081
1	Regulatory	US	**3/20/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Gilead Response to FDA regarding the request for Efficacy and Safety Datasets AMB-220, AMB-222, PK/PD PopPK. NDA 22-081	**2007-03-20_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/19/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Request for Efficacy and Safety Datasets AMB-220, AMB-222, PK/PD PopPK. NDA 22-081	**2007-03-19_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/13/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - The PDF file of Amendment No. 6. NDA 22-081.	**2007-03-13_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/13/2007**	Book 3	FDA Correspondence - Phone	L.Tanner/M.Robb (Phone calls on 03/05/07, 03/06/07, 03/08/07& 03/13/07) - Status feedback Letairis; Meeting request. NDA 22-081	**2007-03-13_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/9/2007**	Book 3	FDA Correspondence - Phone	L.Tanner/S.Gershon - The official contact report with Sharon Gershon regarding the status of the inspection of Dr. Galie (Italy)	**2007-03-09_22081_CORR_EMAIL_LTANNER_SGERSHON.pdf**	22-081
1	Regulatory	US	**3/9/2007**	Book 3	FDA Correspondence - Email	L.Tanner/P.Hinderling - Formatting Changes and Instructions for PI. NDA 22-081	**2007-03-09_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**3/9/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Ambrisentan Questions. NDA 22-081.	**2007-03-09_22081_CORR_EMAIL_MROBB_LTANNER.pdf**	22-081
1	Regulatory	US	**3/8/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb -The e-mail sent to Melissa Robb inquiring about the status of the proprietary name of LETAIRIS. (Note: This question was answered in a teleconference report dated 3-13-07 to Melissa Robb). NDA 22-081	**2007-03-08_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/8/2007**	Book 3	FDA Correspondence - Email	L.Tanner/P.Hinderling - Formatting Changes and Instructions for PI. NDA 22-081	**2007-03-08_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**3/8/2007**	Book 3	FDA Correspondence - Fax	M.Robb/L.Tanner - Teleconference meeting conformation - March 29, 2007. NDA 22-081.	**2007-03-08_22081_CORR_FAX_MROBB_LTANNER.pdf**	22-081

1	Regulatory	US	**3/7/2007**	Book 3	FDA Correspondence - Email	L.Tanner/P.Hinderling - Unformatted PI for Ambrisentan; NDA 22-081; Option to resolve formatting PI.	**2007-03-07_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**3/6/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Gordon - Formal Response on Clinically Significant Abnormal ECGs. NDA 22-081.	**2007-03-06_22081_CORR_EMAIL_LTANNER_MGORDON.pdf**	22-081
1	Regulatory	US	**3/6/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - Unformatted PI for Ambrisentan - No need to submit to the NDA. 22-081.	**2007-03-06_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/5/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb/P.Hinderling - Unformatted PI for Ambrisentan; NDA 22-081.	**2007-03-05_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/3/2007**	Book 3	FDA Correspondence - Email	L.Tanner/M.Robb - request for the meeting to discuss status of review of NDA 22-081. Update on Amendments submitted to NDA. Amendment 5 attached.	**2007-03-03_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**3/2/2007**	Book 3	FDA Correspondence - Phone	L.Tanner/P.Hinderling - Request for unformatted PI for internal edits. NDA 22-081	**2007-03-02_22081_CORR_PHONE_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**2/27/2007**	Book 2	FDA Correspondence - Email	L.Tanner/M.Gordon - The initial response regarding clinically significant abnormal ECGs which was submitted to Mary Gordon on 02/27/07. NDA 22-081	**2007-02-27_22081_CORR_EMAIL_LTANNER_MGORDON.pdf**	22-081
1	Regulatory	US	**2/22/2007**	Book 2	FDA Correspondence - CD-ROM	Desk Copy Request for Phase I CRF's. NDA 22-081	**Request_for_Phase_I_CRFS- Desk _Copy**	22-081
1	Regulatory	US	**2/21/2007**	Book 2	FDA Correspondence - Phone	L.Tanner/M.Robb - Response to Filing Communication; Process for Submitting Completed Nonclinical Study not previously submitted in the NDA; Process for requesting meeting to discuss status of NDA. 22-081.	**2007-02-21_22081_CORR_PHONE_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**2/21/2007**	Book 2	FDA Correspondence - Email	L.Tanner/M.Gordon. The FDA e-mail contact report that provides the plan to provide Maryann Gordon the CRFs that were not previously submitted for subjects who discontinued from Phase 1 studies. NDA 22-081.	**2007-02-21_22081_CORR_EMAIL_LTANNER_MGORDON.pdf**	22-081

1	Regulatory	US	2/20/2007	Book 2	FDA Correspondence - Email	The E-mail with Maryann Gordon regarding our intention to provide the CRF for Subject 38 in Study EE-001. NDA 22-081	2007-02-20_22081_CORR_EMAIL_LTANNER_MGORDON.pdf	22-081
1	Regulatory	US	2/16/2007	Book 2	FDA Correspondence - Letter	N.Stockbridge/M.Gerber - Filling Communication. Filling accepted and priority filling granted. NDA 22-081.	2007-02-16_22081_CORR_LETTER_NSTOCKBRIDGE_MGERBER.pdf	22-081
1	Regulatory	US	2/16/2007	Book 2	FDA Correspondence - Phone	L.Tanner/M.Robb - Phone on 02/13/07, 02/14/07, 02/16/07 to confirm status of NDA filing letter and process for formally submitting responses that have already been emailed to reviewers. NDA 22-081	2007-02-16_22081_CORR_PHONE_LTANNER_MROBB.pdf	22-081
1	Regulatory	US	2/16/2007	Book 2	FDA Correspondence - Email	L.Tanner/M.Robb - RE: NDA 22-081; Status of Feedback Regarding Acceptability of Trade name LETAIRIS (Amendment No. 1)	2007-02-16_22081_CORR_EMAIL_MROBB_LTANNER.pdf	22-081
1	Regulatory	US	2/16/2007	Book 2	FDA Correspondence - Email	L.Tanner/M.Robb - E-mail response to Melissa Robb regarding how refills would be handled in the RiskMAP.	2007-02-16_22081_CORR_EMAIL_LTANNER_MROBB.pdf	22-081
1	Regulatory	US	2/15/2007	Book 2	FDA Correspondence - Email	L.Tanner/P.Hinderling - Summary of PT and INR Methodology. Protime Summary Information doc. Attached.	2007-02-15_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf	22-081
1	Regulatory	US	2/14/2007	Book 2	FDA Correspondence - Phone	Phone - Nikolas Burlew (Regulus Pharmaceutical) called Nancy Schmidt (FDA-Denver District) to establish registration for Gilead Colorado.	2007-02-14_22081_CORR_PHONE_NBURLEW_NSCHMIDT.pdf	22-081
1	Regulatory	US	2/14/2007	Book 2	FDA Correspondence - Email	M.Robb/L.Tanner/ - Email from M. Robb with additional question.(Ambrisentan and RiskMAP). NDA 22 81	2007-02-14_22081_CORR_EMAIL_LTANNER_MROBB.pdf	22-081
1	Regulatory	US	2/14/2007	Book 2	FDA Correspondence - Email	L.Tanner/P.Hinderling - Email indicating that Gilead is continuing to work with our vendor to obtain the PT and INR methodology for AMB-106. NDA 22-081	2007-02-14_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf	22-081
1	Regulatory	US	2/13/2007	Book 2	FDA Correspondence - Phone	L.Tanner/M.Robb - Confirm for handling requests directly from reviewer. E-mail dated 2/13/07 regarding RiskMAP and distribution. Filling Letter.	2007-02-13_22081_CORR_PHONE_LTANNER_MROBB.pdf	22-081

1	Regulatory	US	**2/13/2007**	Book 2	FDA Correspondence - Email	L.Tanner/M.Robb - Gilead response to the questions from FDA on the distribution of Ambrisentan and RiskMAP. The patient enrollment form attached. NDA 22-081	**2007-02-13_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**2/12/2007**	Book 2	FDA Correspondence - Phone	M.Gordon/H.Isokoski. Maryann Gordon called and request to talk to L. Tanner. NDA 22-081	**2007-02-12_22081_CORR_PHONE_MGORDON_HISOKOSKI.pdf**	22-081
1	Regulatory	US	**2/12/2007**	Book 2	FDA Correspondence - Email	M.Gordon/L.Tanner - Another E-mail from Maryann Gordon asking that we submit all clinical information sent to her formally to the NDA.	**2007-02-12_22081_CORR_EMAIL_MGORDON_LTANNER.pdf**	22-081
1	Regulatory	US	**2/12/2007**	Book 2	FDA Correspondence - Email	M.Gordon/L.Tanner - E-mail contact report with Maryann Gordon regarding regenerating a table for LFTs from AMB-222 for archival in the database.	**2007-02-12_22081_CORR_EMAIL_LTANNER_MGORDON.pdf**	22-081
1	Regulatory	US	**2/12/2007**	Book 2	FDA Correspondence - Email	L.Tanner/M.Robb - FDA questions on the distribution of Ambrisentan and RiskMAP.	**2007-02-12_22081_CORR_EMAIL_LTANNER_MROBB.pdf**	22-081
1	Regulatory	US	**2/9/2007**	Book 2	FDA Correspondence - Phone	L.Tanner/M.Gordon - Confirm the requirements for clinical information requested in emails dated 02/07/07 & 02/09/07.	**2007-02-09_22081_CORR_PHONE_LTANNER_MGORDON.pdf**	22-081
1	Regulatory	US	**2/9/2007**	Book 2	FDA Correspondence - Email	L.Tanner/M.Gordon - email sent to M.Gordon regarding her request for additional clinical information. The e-mail contains all of the attachments. NDA 22-081.	**2007-02-09_22081_CORR_EMAIL_LTANNER_MGORDON.pdf**	22-081
1	Regulatory	US	**2/9/2007**	Book 2	FDA Correspondence - Email	E-mail from Peter Hinderling conforming that he received the replacement pages for EE-002	**2007-02-09_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**2/8/2007**	Book 2	FDA Correspondence - Email	E-mail that was submitted to Peter Hinderling, Clinical Pharmacology Reviewer, which contains the replacement pages with figures that are easier to read from EE-002 at his request.	**2007-02-08_22081_CORR_EMAIL_LTANNER_PHINDERLING.pdf**	22-081
1	Regulatory	US	**2/8/2007**	Book 2	FDA Correspondence - Email	L.Tanner/M.Gordon - Conformation of Teleconference on Friday, February 9, 10:00 a.m. EST	**2007-02-08_22081_CORR_EMAIL_LTANNER_MGORDON.pdf**	22-081

1	Regulatory	US	**2/8/2007**	Book 2	FDA Correspondence - Phone	M.Gordon/L.Tanner - Schedule time for teleconference to discuss process for capturing lab values.	**2007-02-08_22081_CORR_PHONE_MGORDON_LTANNER.pdf**	22-081
1	Regulatory	US	**2/6/2007**	Book 2	FDA Correspondence - Phone	H.Isokoski/P.Hinderling - The Methodology to determine Prothrombin Time (PT) and International Normalized Ratio (INR) in AMB-106 and Legible Figures for the report EE-002.	**2007-02-06_22081_CORR_PHONE_PHINDERLING_HISOKOSKI.pdf**	22-081
1	Regulatory	US	**2/5/2007**	Book 2	FDA Correspondence - Email	L.Tanner/M.Robb - E-mail correspondence; Request for Location QTc documentation; Clinical Pharmacology Summary Table. The FDA Response, 2006 Clin. Final IB and FDA Notification App. Attached.	**2007-02-05_22081_CORR_EMAIL_LTANNER_MROBB_.pdf**	22-081
1	Regulatory	US	**2/2/2007**	Book 1	FDA Correspondence - Email	L.Tanner/S.Gershon - Confirm that CD's were sent with information for Clinical Inspections. Attached to the email is the cover letter.	**2007-02-02_22081_CORR_EMAIL_LTANNER_SGERSHON.pdf**	22-081
1	Regulatory	US	**2/2/2007**	Book 1	FDA Correspondence - Phone	L.Tanner/M.Gordon - Confirm that Maryann Gordon was able to retrieve the CRF for Subject 109-002.	**2007-02-02_22081_CORR_PHONE_MGORDON_LTANNER.pdf**	22-081
1	Regulatory	US	**2/2/2007**	Book 1	FDA Correspondence - CD-ROM	Desk Copy Request for Site Specific Information. NDA 22-081	**Clinical_Inspection_Request-Desk_Copy**	22-081
1	Regulatory	US	**2/1/2007**	Book 1	FDA Correspondence - Phone	E.Smith/L.Tanner & M.Plamondon - E.Smith of the Denver District Office of the FDA called regarding the ambrisentan NDA.	**2007-02-01_22081_CORR_PHONE_ESMITH_LTANNER_MPLAMONDON_.pdf**	22-081
1	Regulatory	US	**2/1/2007**	Book 1	FDA Correspondence - Phone	L.Tanner/M.Gordon - Clarify whether CRF for Subject 109-002 was submitted in NDA	**2007-02-01_22081_CORR_PHONE_LTANNER_MGORDON.pdf**	22-081
1	Regulatory	US	**2/1/2007**	Book 1	FDA Correspondence - Email	S.Gershon/L.Tanner - Conform Information to be provided on CD's; Clinical Inspections NDA 22-081.	**2007-02-01_22081_CORR_EMAIL_SGERSHON_LTANNER.pdf**	22-081
1	Regulatory	US	**1/31/2007**	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - Conformation that CRF's for subject 156-007 and 126-008 was received at FDA.	**2007-01-31_22081_CORR_EMAIL_LTANNER_MROBB_156-007.pdf**	22-081

1	Regulatory	US	1/30/2007	Book 1	FDA Correspondence - Phone	L.Tanner/S.Gershon - Confirm acceptability of listings that will be included in the information package on the CDs that will be submitted to her for use during the FDA clinical inspections.	2007-01-30_22081_CORR_PHONE_LTANNER_SGERSHON.pdf	22-081
1	Regulatory	US	1/30/2007	Book 1	FDA Correspondence - Phone	L.Tanner/M.Robb - Confirm that Amendment #2 was received at FDA on January 30, 2007. NDA 22-081.	2007-01-30_22081_CORR_PHONE_LTANNER_MROBB_156-007.pdf	22-081
1	Regulatory	US	1/30/2007	Book 1	FDA Correspondence - Phone	L.Tanner/M.Gordon - Death of female subject (221-003) enrolled in the extension study (AMB-32/321-3). NDA 22-081	2007-01-30_22081_CORR_PHONE_LTANNER_MGORDON.pdf	22-081
1	Regulatory	US	1/26/2007	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - CRF for Subject 156-007 requested by Dr. Marciniak; NDA 22-081. (156-007.zip attached)	2007-01-26_22081_CORR_EMAIL_LTANNER_MROBB_156-007.pdf	22-081
1	Regulatory	US	1/26/2007	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - CRF for subject 126-008 requested by Dr. Marciniak; NDA 22-081. (126-008.zip attached)	2007-01-26_22081_CORR_EMAIL_LTANNER_MROBB_126-008.pdf	22-081
1	Regulatory	US	1/26/2007	Book 1	FDA Correspondence - Email	L.Tanner/S.Gershon - Confirm information to be provided on CD's; Clinical Inspections NDA 22-081	2007-01-26_22081_CORR_EMAIL_LTANNER_SGERSHON.pdf	22-081
1	Regulatory	US	1/25/2007	Book 1	FDA Correspondence - Phone	L.Tanner/S.Gershon - Reminder for non-USA contact information for Site #207 (Nazzareno Galie, Italy) NDA 22-08.	2007-01-25_22081_CORR_PHONE_LTANNER_SGERSHON.pdf	22-081
1	Regulatory	US	1/25/2007	Book 1	FDA Correspondence - Email	L.Tanner/S.Gershon - Contact Information Italian Inspector; NDA 22-081 (ambrisentan)	2007-01-25_22081_CORR_EMAIL_LTANNER_SGERSHON.pdf	22-081
1	Regulatory	US	1/25/2007	Book 1	FDA Correspondence - Email	S.Gershon/ L.Tanner - Contact Person in Italy.	2007-01-25_22081_CORR_EMAIL_SGERSHON_LTANNER_.pdf	22-081
1	Regulatory	US	1/23/2007	Book 1	FDA Correspondence - Email	M.Robb/L.Tanner - Email - Response from FDA to the letter dated 1/11/07. Re: Submission of complete CRF's: NDA 022-081.	2007-01-23_22081_CORR_EMAIL_MROBB_LTANNER_.pdf	22-081
1	Regulatory	US	1/22/2007	Book 1	FDA Correspondence - Email	S.GershonL/Tanner - Email regarding Revised Protocol Document - Presence of Sponsors Clinical Investigations.	2007-01-22_22081_CORR_EMAIL_SGERSHON_LTANNER_.pdf	22-081

1	Regulatory	US	1/19/2007	Book 1	FDA Correspondence -Phone	S.GershonL/Tanner - Phone regarding FDA inspections at clinical sites that conducted Phase 3 studies AMB-320 or AMB-321.	2007-01-19_22081_CORR_PHONE_SGERSHON_LTANNER_.pdf	22-081
1	Regulatory	US	1/19/2007	Book 1	FDA Correspondence - Email	L.Tanner/S.Gershon. Email regarding revised protocol documents. AMB-321 & AMB 320 protocols attached.	2007-01-19_22081_CORR_EMAIL_LTANNER_SGERSHON.pdf	22-081
1	Regulatory	US	1/19/2007	Book 1	FDA Correspondence - Email	S.Gershon/ L.Tanner - Email regarding NDA 22-081 Letairis . Respond from CDER about DSI inspections.	2007-01-19_22081_CORR_EMAIL_SGERSHON_LTANNER_.pdf	22-081
1	Regulatory	US	1/18/2007	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - Response to FDA Letter Dated 1/11/07 Re: Submission of Complete CRF's, NDA 022-081	2007-01-18_22081_CORR_EMAIL_MROBB_LTANNER_.pdf	22-081
1	Regulatory	US	1/16/2007	Book 1	FDA Correspondence - Phone	L.Tanner/M.Robb - Follow-up on response to Division regarding re-submission of CRF's and filing process.	2007-01-16_22081_CORR_PHONE_MROBB_LTANNER_.pdf	22-081
1	Regulatory	US	1/16/2007	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - Clarification on the requested presented during the teleconference on 1/9/07. The Response to Division regarding re-submission of CRF's and filing	2007-01-16_22081_CORR_EMAIL_MROBB_LTANNER_.pdf	22-081
1	Regulatory	US	1/11/2007	Book 1	FDA Correspondence - Letter	Letter from E.Fromm/M.Gerber. Discipline Review Letter - CRF's Forms in the NDA 20-081	2007-01-11_22081_CORR_LETTER_EFROOM_MGERBER.pdf	22-081
1	Regulatory	US	1/11/2007	Book 1	FDA Correspondence - Email	Email from M. Robb to H.Isokoski with the discipline review letter from FDA.	2007-01-11_22081_CORR_EMAIL_MROBB_HISOKOSKI_1.pdf	22-081
1	Regulatory	US	1/11/2007	Book 1	FDA Correspondence - Email	H.Isokoski/M.Robb - Email. Clarification on the requested, presented during the teleconference on 01/09/07.	2007-01-11_22081_CORR_EMAIL_MROBB_HISOKOSKI_.pdf	22-081
1	Regulatory	US	1/11/2007	Book 1	FDA Correspondence - Phone	H.Isokoski/M.Robb - Three phone calls. Clarification on the teleconference held on 01/09/07.	2007-01-11_22081_CORR_PHONE_HISOKOSKI_MROBB.pdf	22-081
1	Regulatory	US	1/10/2007	Book 1	FDA Correspondence - Letter	E.Fromm/L.Tanner - FDA letter that acknowledges that the date of receipt of NDA 22-081 was December 18, 2006. The official filing data will be February 16, 2007	2007-01-10_22081_CORR_LETTER_EFROOM_LTANNER.pdf	22-081

1	Regulatory	US	**1/9/2007**	Book 1	FDA Correspondence - Phone	Gilead Teleconference Meeting Minutes with FDA - T. Marciniak.	**2007-01-09_22081_CORR_PHONE_MEETING_MINUTES_TMARCINIAK_HISOKOSKI.pdf**	22-081
1	Regulatory	US	**1/5/2007**	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - Email. Confirmation of teleconference scheduled for Tuesday, January 9, 2007 with the FDA.	**2007-01-05_22081_CORR_EMAIL_MROBB_LTANNER_.pdf**	22-081
1	Regulatory	US	**1/5/2007**	Book 1	FDA Correspondence - Phone	L.Tanner/M.Robb - Phone To Confirm date and participants for teleconference with the FDA.	**2007-01-05_22081_CORR_PHONE_MROBB_LTANNER_.pdf**	22-081
1	Regulatory	US	**12/19/2006**	Book 1	FDA Correspondence - Phone	L.Tanner/M.Robb - Feedback from M. Robb regarding the process for responding to the Division of DMETS regarding the acceptability of LETAIRIS. Attached FDA contact report from 12/18/2006 per L. Tanner.	**2006-12-19_22081_CORR_PHONE_MROBB_LTANNER_.pdf**	22-081
1	Regulatory	US	**12/19/2006**	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - Confirmation from M.Robb that the submission NDA 22-081 was received at document room.	**2006-12-19_22081_CORR_EMAIL_MROBB_LTANNER_.pdf**	22-081
1	Regulatory	US	**12/18/2006**	Book 1	FDA Correspondence - Email	L.Tanner/M.Robb - Conformation that NDA 22-081 was received at FDA Mail Room.	**2006-12-18_22081_CORR_EMAIL_MROBB_LTANNER_.pdf**	22-081